OPTI LION

English Operator's Manual

PD7200
OPERATOR'S MANUAL REVISION LOG
(Please record any changes made to this manual)

<table>
<thead>
<tr>
<th>Revision Number</th>
<th>Release Date</th>
<th>Approved By</th>
<th>Description</th>
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PD7200 REV E
This Operator's Manual contains important warnings and safety information to be observed by the user.

This instrument is only intended for one area of application which is described in the instructions. The most important prerequisites for application, operation and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is applied in areas other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument is only to be operated by qualified personnel capable of observing these prerequisites.

Only accessories and supplies either delivered by or approved by OPTI Medical are to be used with the instrument.

Due to this instrument’s operating principle, analytical accuracy not only depends on correct operation and function, but also upon a variety of external influences beyond the manufacturer's control. Therefore, the test results from this instrument must be carefully examined by an expert, before further measures are taken based on the analytical results.

Treatment should never be administered based on results that are flagged on the printout.

Instrument adjustment and maintenance with removed covers and connected power mains are to be performed only by a qualified technician who is aware of the dangers involved.

Instrument repairs are to be performed only by the manufacturer or qualified service personnel.
Operating Safety Information

- Overvoltage Category II when connected to a branch circuit.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules.

Caution:

- The instrument is designed as a conventional device (closed, not waterproof type).
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- This instrument is suitable for continuous operation.
- The power plug is to be plugged into a ground socket only. When using an extension cord, make sure that it is of the proper size and is properly grounded.
- Any breakage of the ground lead inside or outside the instrument or a loose ground connection can cause a hazardous condition when operating the instrument. Intentional disconnection of the grounding is not permitted.
- When replacing the fuses, make sure that they are of the same type and rating as the original fuses. Never use repaired fuses or short-circuit the fuse holders.
## Symbol Definitions

The symbols described below are used on the packaging of OPTI® LION related products.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td><strong>Attention Symbol</strong> – Refer to the Operator’s Manual or Service Manual for further instructions. This symbol is located on the inside of the instruments and product packaging.</td>
</tr>
<tr>
<td>EXP 🕋</td>
<td><strong>Expiration / Use By Symbol</strong> – Product to be used by the expiration date indicated to the right of this symbol. This symbol is located on all consumables, which are controlled via an expiration or use by date.</td>
</tr>
<tr>
<td>📝</td>
<td><strong>Batch Code Symbol</strong> – Manufacturing lot number is located to the right of this symbol. This symbol is located on all products, which are controlled via a lot number.</td>
</tr>
<tr>
<td>🚫</td>
<td><strong>Do Not Re-use Symbol</strong> – Identifies products which are not to be used for more than the specified period of time as defined in the product instructions. This symbol is located on all applicable product packaging.</td>
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<tr>
<td>🔄</td>
<td><strong>Recycle Plastic Symbol</strong> - Identifies the clear plastic material (polyethylene terephthalate glycol) used in the packaging of the product. Containers identified with this symbol can be considered recyclable. This symbol is located on all applicable product packaging.</td>
</tr>
<tr>
<td>🚮</td>
<td><strong>WEEE-Symbol</strong> - This product complies with WEEE Directive 2002/96/EC which mandates the treatment, recovery and recycling of electric and electronic equipment.</td>
</tr>
<tr>
<td>Symbol</td>
<td>Explanation</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image" alt="Bio-Hazard Symbol" /></td>
<td>Bio-Hazard Symbol – Products and/or components containing this symbol should be handled as bio-hazardous material after use.</td>
</tr>
<tr>
<td><img src="image" alt="Temperature Limit Symbol" /></td>
<td>Temperature Limit Symbol – Products and/or components which contain this symbol must be stored within the specified temperature range.</td>
</tr>
<tr>
<td><img src="image" alt="IVD" /></td>
<td>For in vitro diagnostic use</td>
</tr>
<tr>
<td><img src="image" alt="CE" /></td>
<td>This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.</td>
</tr>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Catalog number</td>
</tr>
<tr>
<td><img src="image" alt="i" /></td>
<td>Please read pack insert. / Follow the instrument’s instructions for use!</td>
</tr>
<tr>
<td><img src="image" alt="Manufactured by" /></td>
<td>Manufactured by</td>
</tr>
<tr>
<td><img src="image" alt="Authorized European Community Representative" /></td>
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</tbody>
</table>
PREFACE

Welcome

Your OPTI® LION Electrolyte Analyzer is a powerful tool designed to help you quickly, accurately and efficiently conduct basic testing of Na⁺, K⁺, Cl⁻, iCa and pH in the convenience of your own laboratory.

This manual will help guide you through setting up your analyzer and will help you start analyzing samples. As you become familiar with the operation of the unit, you should use the manual as a reference for day-to-day routines and as a guide for maintenance and troubleshooting.

How to use this manual

If you have an analyzer that is not yet set up, you should begin by reading Chapters 1 and 2. For programming and quality control functions, read Chapters 3 and 4. Information on analyzer operation and maintenance is contained in Chapters 5 and 6. Detailed service information and operating principles can be found in Chapters 7 and 8.
**Potassium**

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, hyperkalemia, can be found in oliguria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K⁺/H⁺ exchange and hemolysis of the blood. Low potassium levels, hypokalemia, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea, hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

**Chloride**

Chloride is an anion that exists predominantly in extracellular spaces. It maintains cellular integrity through its influence on osmotic pressure. It is also significant in monitoring acid-base balance and water balance. In metabolic acidosis, there is a reciprocal rise in chloride concentration when the bicarbonate concentration drops.

Decreased levels are found in severe vomiting, severe diarrhea, ulcerative colitis, pyloric obstruction, severe burns, heat exhaustion, diabetic acidosis, Addison’s disease, fever and acute infections such as pneumonia.

Increased levels are found in dehydration, Cushing’s syndrome, hyperventilation, eclampsia, anemia and cardiac decompensation.

**Ionized Calcium**

Calcium in blood is distributed as free calcium ions (50%); bound to protein, mostly albumin (40%); and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI LION measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, hypercalcemia, is found in patients with increased intestinal absorption, increased mobilization from bone (osteolysis), decreased renal elimination, hyperparathyroidism and Addison’s disease. Hypercalcemia may also be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.
Decreased calcium, hypocalcemia, is found in patients with decreased intestinal absorption, increased renal elimination, increased deposition of calcium in the bones, increased binding to proteins when the pH increases or binding to citrate, and hypoparathyroidism.

Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease\(^2\).

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Ionized calcium may be reported either as the actual ionized calcium, referred to actual pH of the patients, or as normalized ionized calcium, to a standard pH at pH 7.40. The binding of calcium by protein and small anions is influenced by pH and because of this relationship specimens should be analyzed at the pH of the patient’s blood.

For more detailed information about the preanalytical variables affecting ionized calcium, please refer to the most current edition of NCCLS document C31- Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling.

**pH**

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis
b) primary bicarbonate excess - metabolic alkalosis
c) primary hypoventilation - respiratory acidosis
d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO\(_2\), due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H\(^+\) ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or may be chronic; as the result of obstructive or restrictive respiratory diseases.

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**Principles of Procedure**

Luminescence is the emission of light energy resulting from excited molecules returning to a resting state. When luminescence is initiated by light, it is commonly referred to as fluorescence. When a fluorescent chemical is exposed to light energy of an appropriate color, electrons in the molecules of the fluorescent chemical are excited. A very short time later, the electrons return to a resting state and in this process sometimes emit a small amount of light energy. This energy is less than the excitation energy and therefore has a different color. That is, the emitted light (fluorescence emission), is red-shifted from the excitation light, and is much less intense.³

Fluorescent optodes (from optical electrodes) measure the intensity of light emitted from fluorescent dyes exposed to a specific analyte. The emitted light is distinguished from excitation light by means of optical filters. Because the excitation light energy is kept constant, the small amount of light that results is changed only by the concentration of the analyte. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a known calibration point and that measured with the unknown concentration of analyte.

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titration in turbid media.

The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry,

\[
\frac{I_0}{I} = \frac{10^{pK_a - pH} + 1}{10^{pK_a - pH} + R}
\]

which describes how the fluorescence emission intensity decreases as the blood pH is increased above the dye’s characteristic pKa. R is the ratio of minimum fluorescent intensity (pH >> pKa) to maximum fluorescent intensity (pH << pKa). pH optodes do not need a reference electrode to measure pH, however, they exhibit a small sensitivity to the ionic strength of the sample being measured.⁴

The Na⁺, K⁺, Cl⁻ and iCa ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970’s to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters.⁵ As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI LION using the measured pH.

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**Operation**

The OPTI LION is a microprocessor-based instrument measuring optical fluorescence.

A disposable, single-use cassette contains all the elements needed for calibration, sample measurement and waste containment. After reading the calibration information specific to the cassette into the instrument by ‘swiping’ the cassette package bar code through a convenient bar code reader, the cassette is placed into the measurement chamber. The analyzer warms the cassette to 37.0 ± 0.1 °C, and performs a calibration verification on the electrolyte and pH channels. The calibration verification is performed on the fluorescent sensors in a stable dry state with a proprietary, well-defined bar-coded relationship to their mid-physiologic wet state, essentially providing a mid-physiologic calibration verification.

When calibration is verified, the analyzer aspirates the blood sample into the cassette and across the optode sensors. Fluorescence emission is then measured after equilibrating with the blood sample. After a single measurement, the cassette, containing the blood sample, is removed from the analyzer and discarded. The analyzer contains no reagents, blood or waste.

During each measurement, light originating from lamps in the analyzer is passed through optical filters so that photons of a specific color are transmitted to the sensors, causing them to emit fluorescence. The intensity of this emitted light depends upon the electrolyte concentration (Na⁺, K⁺, Cl⁻, iCa) and hydrogen ion concentration (pH) of the blood in direct contact with the sensors, as described above.

The light emitted by the fluorescent sensors is measured by the analyzer after passing through lenses and additional optical components. A filter is used to isolate specific colors of interest from this returning light for measurement by a light detector.

The output signal of the detectors is converted by the microprocessor to a numeric readout in conventional units of measure and displayed on the front of the device.
**Accessories**

**OPTI LION E-Plus Sensor Cassette, BP7507**

**Use:** For measurement of Na⁺, K⁺, Cl⁻, iCa and pH with the OPTI LION.

**Contents:** Box contains 25 individually packaged cassettes. Each disposable plastic cassette contains optical sensors and a sample probe.

**Composition:** Dry sensors (0% humidity)

**Storage:** Refer to package labeling.

**Stability:** Expiration date and lot number are printed on each package label and encoded on the attached bar code label.

**Standard Reference Cassette (SRC) - Level 1, BP7604**

**Use:** For diagnostic and daily QC check of the OPTI LION

**Contents:** Each package contains one reusable SRC Cassette.

**Composition:** Stabilized optode sensors to verify system within-run and run-to-run intensity stability with assay values:

<table>
<thead>
<tr>
<th>Ion</th>
<th>Assay Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>123.0 - 127.0 mmol/L</td>
</tr>
<tr>
<td>K⁺</td>
<td>2.2 - 2.8 mmol/L</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>78.0 - 82.0 mmol/L</td>
</tr>
<tr>
<td>iCa</td>
<td>1.7 - 1.9 mmol/L</td>
</tr>
<tr>
<td>pH</td>
<td>7.080 - 7.120 pH units</td>
</tr>
</tbody>
</table>

**Storage:** Refer to package labeling.

**Stability:** Expiration date and lot number are printed on each package label and encoded on the attached bar code label.

**Standard Reference Cassette (SRC) - Level 2 (Optional), BP7605**

**Use:** For diagnostic and daily QC check of the OPTI LION

**Contents:** Each package contains one reusable SRC Cassette.

**Composition:** Stabilized optode sensors to verify system within-run and run-to-run intensity stability with assay values:

<table>
<thead>
<tr>
<th>Ion</th>
<th>Assay Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>143.0 - 147.0 mmol/L</td>
</tr>
<tr>
<td>K⁺</td>
<td>4.2 - 4.8 mmol/L</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>103.0 - 107.0 mmol/L</td>
</tr>
<tr>
<td>iCa</td>
<td>1.0 - 1.2 mmol/L</td>
</tr>
<tr>
<td>pH</td>
<td>7.380 - 7.420 pH units</td>
</tr>
</tbody>
</table>

**Storage:** Refer to package labeling.

**Stability:** Expiration date and lot number are printed on each package label and encoded on the attached bar code label.
**Standard Reference Cassette (SRC) - Level 3, BP7606**

**Use:** For diagnostic and daily QC check of the OPTI LION

**Contents:** Each package contains one reusable SRC Cassette.

**Composition:** Stabilized optode sensors to verify system within-run and run-to-run intensity stability with assay values:
- Na\(^+\) 163.0 - 167.0 mmol/L
- K\(^+\) 6.7 - 7.3 mmol/L
- Cl\(^-\) 128.0 - 132.0 mmol/L
- iCa 0.6 - 0.8 mmol/L
- pH 7.580 - 7.620 pH units

**Storage:** Refer to package labeling.

**Stability:** Expiration date and lot number are printed on each package label and encoded to the attached bar code label.

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**Calibration Cassette, BP7607**

**Use:** For diagnostic and periodic calibration of the OPTI LION

**Contents:** Each package contains one reusable Calibration Cassette.

**Composition:** Stabilized optode sensors.

**Storage:** Refer to package labeling.

**Stability:** Expiration date and lot number are printed on each package label and encoded to the attached bar code label.

---

**Precautions**

Use of calibration solutions, sample probe, or optodes not manufactured by OPTI Medical Systems could void the warranty.

Once used, the sample cassette holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact or ingestion.

For *in-vitro* diagnostic use.

For professional use only.
Specimen Collection and Handling

Safety

Universal precautions must be observed when collecting blood specimens. It is recommended that all blood specimens be handled as if capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection techniques must be followed in order to minimize risk to the laboratory staff, and gloves should be worn. Please refer to CLSI document M29-A3, Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition; March 2005, for further information on safe handling of these specimens.

Sample Requirements


Recognition of the need for procedures that address the different areas of specimen collection is evidenced by the following NCCLS documents:

- H1 - Tubes and Additives for Venous Blood Specimen Collection;
- H3 - Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture;
- H4 - Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens;
- H11 - Procedures for the Collection of Arterial Blood Specimens;

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling documentation and specific procedures used approved by the personnel responsible.

Anticoagulants and Sample Collection Devices

The OPTI LION will accept samples from sample collection tubes, sample cups and syringes.

For whole blood and plasma samples, a balanced heparin that does not affect the electrolyte values is the anticoagulant of choice. Sodium herparin is also an acceptable anticoagulant for electrolyte analysis, however, heparin binds ionized calcium to a certain extent, falsely decreasing the measurement values.

Other anticoagulants such as EDTA, citrate, oxalate and fluoride have a significant effect on blood pH and electrolyte levels and should not be used. Lithium heparin should not be used for samples taken also for analysis of lithium.

For serum samples, containers without additives should be used.
Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution.

Handling and Storage of Samples


Whole blood samples should be collected in a sample collection tube or heparinized syringe, and analyzed as soon as possible after collection. Immediately after collection, check the syringe or other device for air bubbles and carefully expel any trapped bubbles, following the manufacturer’s recommended procedure. Extreme caution should be used to avoid needle stick injury. If collected in a syringe or vacuum tube, mix the specimen thoroughly with anticoagulant by gentle inversion or by rolling the syringe between both hands. Properly identify the specimen, following usual procedures for such documentation. Place the syringe containing the specimen in an ice slurry. The pH content will change if the specimen remains at room temperature in a syringe for more than 5 minutes or is exposed to air due to cellular metabolism and the loss of carbon dioxide.

The OPTI LION system aspirates blood in the same manner from sample collection tubes, sample cups and syringes.

No changes are made to the aspiration rate, volume or timing. Therefore, there are no biases or imprecision dependent upon the sample introduction method. Sufficient volume must, however, be present in syringes (0.25 mL in a 1 mL syringe) to prevent mechanical interference between the syringe plunger and the sample probe.

Errors in blood analysis on properly collected samples may result from improper mixing of the sample after collection and before measurement; contamination with room air from either the failure to expel any trapped bubbles after collection or exposing the sample to room air; and from metabolic changes in the sample.

Serum samples should be obtained by collecting blood in an untreated blood collecting tube. The sample should stand for 30 minutes to allow the clot to form prior to centrifugation. After centrifugation, remove the serum from the clot, and cap or seal the sample tube. If storage is required, the sample should be tightly capped preventing continued exposure to air, refrigerated at 4 to 8 °C for no longer than 48 hours, and allowed to return to room temperature, 15 to 30 °C, prior to analysis. Each laboratory should determine the acceptability of its own blood collection syringes, capillaries and tubes and the serum or plasma separation products. Variations in these products exist between manufacturers, and at times, from lot to lot.
**Procedure**

**Materials Needed**

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPTI LION E-Plus Sensor Cassette</td>
<td>BP7507</td>
</tr>
<tr>
<td>Standard Reference Cassette Level 1</td>
<td>BP7604</td>
</tr>
<tr>
<td>Standard Reference Cassette Level 3</td>
<td>BP7606</td>
</tr>
<tr>
<td>Calibration Cassette</td>
<td>BP7607</td>
</tr>
<tr>
<td>OPTI Check Lytes Control Material</td>
<td>HC7010</td>
</tr>
<tr>
<td>Printer Paper</td>
<td>HP0070</td>
</tr>
</tbody>
</table>

The OPTI LION automatically processes the sample through the necessary steps, then displays and prints the results. For details of this operation, please refer to the remainder of the Operator’s Manual.

**Test Conditions**

- **Sample Size:** a minimum of 125 µL
- **Sample Type:** heparinized whole blood, serum, plasma
- **Sample Application:** sample collection tube, sample cup or syringe
- **Ambient Temperature:** 10 - 32 ºC (50 – 90 ºF)
- **Relative Humidity:** 5% to 95% (non-condensing)
- **Type of Measurement:** optical fluorescence

**Measurement Range**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Display Resolution (Lo/Hi)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>100 to 190</td>
<td>1/0.1</td>
<td>mM</td>
</tr>
<tr>
<td>K⁺</td>
<td>1.0 to 9.5</td>
<td>0.1/0.01</td>
<td>mM</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>65 to 145</td>
<td>1/0.1</td>
<td>mM</td>
</tr>
<tr>
<td>iCa</td>
<td>0.3 to 2.0</td>
<td>0.01</td>
<td>mM</td>
</tr>
<tr>
<td>pH</td>
<td>6.8 to 8.0</td>
<td>0.01/0.001</td>
<td>pH units</td>
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**Method Sheet**

### Input Values

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<tr>
<td>Sample Type</td>
<td>Blood/Serum/Plasma</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Patient Sex</td>
<td>male, female or ?</td>
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<td>Patient temperature, T</td>
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<td>°C</td>
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<td>°F</td>
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### Calculated Values

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<th>Units</th>
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<tbody>
<tr>
<td>Hydrogen ion concentration, cH⁺</td>
<td>1000.0 to 10.0</td>
<td>0.1</td>
<td>nmol/L</td>
</tr>
<tr>
<td>nCa</td>
<td>0.22 to 2.79</td>
<td>0.1</td>
<td>mmol/L</td>
</tr>
</tbody>
</table>

### Calibration

The OPTI LION system uses a proprietary dry-calibration process based on the simple, well-defined relationship of fluorescent intensity in the sensor’s dry state to the fluorescent intensity in the sensor’s mid-physiologic wet state at discrete standard analyte levels. This dry-to-wet physiologic relationship is stable and consistent for all sensors within a lot and is characterized and bar-coded by the manufacturer. In addition, the sensor’s wet response curve of fluorescent intensity versus analyte level is characterized and bar-coded analogously with the proven method employed in the OPTI CCA system.

The dry calibration principle relies on a combination of sensor chemistry design, to enable it to fluoresce with predictable intensity consistent from sensor to sensor, and on the sensor and cassette processing and packaging, to ensure a stable and well-defined dry environment. The OPTI LION’s dry calibration is insensitive to ambient humidity because the cassette’s plastic body and the sensor overcoats act as temporary moisture barriers before and during the dry calibration measurement.

Prior to running a sample, the cassette’s bar code is read into the analyzer by ‘swiping’ the cassette package through a conveniently located bar code reader. The cassette is then installed and a calibration is performed. In addition, an optical zero point calibration of all optical channels is performed.
During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, proper cassette temperature control, proper equilibration behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of dirty optics, or worn pump conditions.

Periodic maintenance according to the manufacturer’s recommendation is carried out to ensure consistent performance. A solid calibrator cassette is run followed by a verification solution. This procedure ensures measurement accuracy is maintained over the lifetime of the instrument.

**Quality Control**

On initial use of each lot of cassettes, one level of liquid QC must be run using OPTI Medical electrolyte controls (OPTI CHECK LYTES - HC7010) or equivalent material recommended by OPTI Medical Systems. At 2 month intervals thereafter, an additional QC measurement should be performed to validate the lot. These measurements should provide target values for Na⁺, K⁺, Cl⁻, iCa and pH over a range of measurement values typically seen in each laboratory.

The results obtained should fall within limits defined by the day-to-day variability as measured in the user’s laboratory.

It is recommended to aspirate Quality Control and Proficiency testing material directly from the ampoule. This procedure helps to minimize sensitivity to pre-analytic and other errors associated with the use of aqueous controls (see Limitations Section).

A minimum of two *Standard Reference Cassettes (SRCs)*, of different levels, should be used as a control for measurement and proper analyzer operation. OPTI Medical Systems recommends that the SRC measurement be confirmed within acceptance ranges on both levels once each day of OPTI LION operation. These special test cassettes contain a stable optical sensor simulator which is measured by the device in a manner that assures instrument parameters perform within specified limits when “PASS” status is obtained.

The results obtained should fall within limits supplied with the SRCs. Level 1 and level 3 SRCs are supplied with the analyzer producing low and high Na⁺, K⁺, Cl⁻, iCa and pH values.

An optional, normal range SRC (Level 2) is available from OPTI Medical Systems.

Limit values supplied with the SRCs are:

<table>
<thead>
<tr>
<th></th>
<th>SRC LOW</th>
<th>SRC NORMAL</th>
<th>SRC HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>125.0 ± 2 mmol/L</td>
<td>145.0 ± 2 mmol/L</td>
<td>165.0 ± 2 mmol/L</td>
</tr>
<tr>
<td>K⁺</td>
<td>2.5 ± 0.3 mmol/L</td>
<td>4.5 ± 0.3 mmol/L</td>
<td>7.0 ± 0.3 mmol/L</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>80.0 ± 2 mmol/L</td>
<td>105.0 ± 2 mmol/L</td>
<td>130.0 ± 2 mmol/L</td>
</tr>
<tr>
<td>iCa</td>
<td>1.8 ± 0.1 mmol/L</td>
<td>1.1 ± 0.1 mmol/L</td>
<td>0.7 ± 0.1 mmol/L</td>
</tr>
<tr>
<td>pH</td>
<td>7.100 ± 0.02 pH</td>
<td>7.400 ± 0.02 pH</td>
<td>7.600 ± 0.02 pH</td>
</tr>
</tbody>
</table>

All specific performance specifications reported in this summary are determined from the above, minimal recommendations for quality control verification.
The OPTI LION’s equivalent QC method, Standard Reference Cassette (SRC), is a relatively new concept in quality control testing. In traditional electrolyte analyzers, liquid quality control (QC) material is run several times a day to verify the system measurement, including reagents, used for patient testing. On these systems, multiple patient samples are run using the same reagent system.

The traditional method of running a liquid QC material several times each day does not check these individual reagent and sensor systems. Therefore, manufacturers have developed equivalent QC methods to ensure all elements of the system are monitored. OPTI Medical Systems has a two-step approach. First the SRC, the OPTI LION’s electronic/optical simulator, checks the electronics, optics, thermostats, etc. of the system. Second, when a sample cassette is inserted, the OPTI LION performs an extensive quality check prior to patient sampling to ensure, among other things, that the measurement system contained within the cassette is within pre-defined limits. If the sensor cassette is not, an error message occurs and the cassette is discarded.

In addition, automatic checks are performed of packaging integrity, temperature control, bubble detection, etc. This approach provides a quality control check of the system similar to traditional liquid QC without incurring additional costs to the laboratory.

Every hospital is required to develop its own policies and procedures for quality control checks. Minimum guidelines are defined by a variety of regulatory agencies. Many agencies have updated their regulations to incorporate equivalent QC methods such as the SRC. Some, however, have not.

For agencies requiring a liquid QC material and for institutions requiring additional QC checks, OPTI CHECK LYTES is available.

OPTI CHECK LYTES is a specially formulated aqueous liquid control material that contains all analytes measurable by the OPTI LION.

OPTI CHECK LYTES provides a method of performing daily QC checks for laboratories selecting to measure liquid QC material.
Reference Intervals

Reference intervals are useful in describing typical results found in a defined population of apparently healthy people. Reference intervals should not, however, be used as absolute indicators of health and disease due to variability among methods, laboratories, locations and other considerations. The reference intervals presented here are for **general informational purposes only**. Guidelines for defining and determining reference intervals are published in the 2000 NCCLS C28-A2 guideline (How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition.) Individual laboratories should generate their own set of reference intervals.

**Sodium**

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Range, mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>Premature, 48 hr</td>
<td>128-148</td>
</tr>
<tr>
<td>Newborn</td>
<td>133-146</td>
</tr>
<tr>
<td>Infant</td>
<td>139-146</td>
</tr>
<tr>
<td>Child</td>
<td>138-145</td>
</tr>
<tr>
<td>Adult</td>
<td>136-145</td>
</tr>
<tr>
<td>&gt;90 yr</td>
<td>132-146</td>
</tr>
</tbody>
</table>

**Potassium**

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Range, mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>Premature, 48 hr</td>
<td>3.0-6.0</td>
</tr>
<tr>
<td>Newborn</td>
<td>3.7-5.9</td>
</tr>
<tr>
<td>Infant</td>
<td>4.1-5.3</td>
</tr>
<tr>
<td>Child</td>
<td>3.4-4.7</td>
</tr>
<tr>
<td>Adults</td>
<td>3.5-5.1</td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3.5-4.5</td>
</tr>
<tr>
<td>Female</td>
<td>3.4-4.4</td>
</tr>
</tbody>
</table>

**Chloride**

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Range, mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum and plasma</td>
<td></td>
</tr>
<tr>
<td>Premature</td>
<td>95-110</td>
</tr>
<tr>
<td>0-30 days</td>
<td>98-113</td>
</tr>
<tr>
<td>Adult</td>
<td>98-107</td>
</tr>
<tr>
<td>&gt;90 yr</td>
<td>98-111</td>
</tr>
</tbody>
</table>

**Ionized Calcium**

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Range, mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum and plasma</td>
<td></td>
</tr>
<tr>
<td>Adults</td>
<td>1.15-1.33</td>
</tr>
</tbody>
</table>

---

pH

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood, arterial</td>
<td></td>
</tr>
<tr>
<td>Premature newborn, 48 hr</td>
<td>7.35-7.50</td>
</tr>
<tr>
<td>Full term, birth</td>
<td>7.11-7.36</td>
</tr>
<tr>
<td>Full term, 1 day</td>
<td>7.29-7.45</td>
</tr>
<tr>
<td>Children, adults</td>
<td>7.35-7.45</td>
</tr>
</tbody>
</table>

Specific Performance Characteristics

All performance data in this section was generated on OPTI LION systems with the SRC run daily to check QC. Quality control material was run with each new lot of cassettes.

Limitations

The performance characteristics are affected by the following sample considerations:

The preferred test liquid is whole human blood or human serum/plasma for all parameters.

pH of blood cannot be predicted in tonometry. All tonometered blood/plasma samples analyzed in these studies were analyzed in duplicate on an AVL 995 to establish correlation. Precision pH measurement was evaluated over a 20 day period using two OPTI LION systems with two replicates per run and two runs per day using control materials.

Measuring Range:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>100 to 190</td>
<td>mmol/L</td>
</tr>
<tr>
<td>K⁺</td>
<td>1.0 to 9.5</td>
<td>mmol/L</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>65 to 145</td>
<td>mmol/L</td>
</tr>
<tr>
<td>iCa</td>
<td>0.3 to 2.0</td>
<td>mmol/L</td>
</tr>
<tr>
<td>pH</td>
<td>6.8 to 8.0</td>
<td>pH units</td>
</tr>
</tbody>
</table>

Any measurement outside the Measurement Range will be indicated on the display as ‘LOW’ for values lower than the range and ‘HIGH’ for values above the range. However, the printed report will show out-of-range values with reference to the end value of the measurement range; for example, the printed report will show a Na⁺ value of 200 mmol/L as:

Na⁺ > 190 mmol/L (Meas.Lim)
**Interferences**

Optode pH measurements have a known sensitivity to the blood ionic strength\(^7\), which is determined primarily by variation in serum levels of sodium. The OPTI LION utilizes an internal Na\(^+\) sensor to actively compensate and correct for this sensitivity. That is, the OPTI LION’s reported pH has no significant interference from hyponatremic or hypernatremic samples, nor for ionic strength variations within the physiologic limits of 100 to 190 mmol/L.

The OPTI LION K\(^+\) sensor has no significant interference from Na\(^+\) variation within the range 100-190 mmol/L. The OPTI LION Na\(^+\) sensor has no significant interference from K\(^+\) variation within the range 0.8-10 mmol/L.

The OPTI LION K\(^+\) sensor has no significant interference from ammonia or ammonium ion present at normal physiologic levels (below 100 µmol/L). At hyperammonemia (plasma levels of 300 µmol/L), the OPTI LION K\(^+\) sensor will show a potassium offset of +0.4 mmol/L, and at extreme hyperammonemia (plasma levels of 3000 µmol/L), the OPTI LION K\(^+\) sensor will show a potassium offset of +4.4 mmol/L.

The OPTI LION Na\(^+\) sensor does exhibit a small interference from Li\(^+\). Li\(^+\) levels of 1.0, 2.5, and 6.4 mmol/L will cause a positive Na\(^+\) bias of 0.9, 1.2, and 1.3 mmol/L, respectively. A syringe sample anticoagulated with typical amounts of lithium heparin has 1-4 mmol/L of lithium, which offsets the measured Na\(^+\) by less than 1%.

To minimize the interference from lithium, use syringes containing the lowest acceptable heparin level. Carefully follow the syringe manufacturer’s recommendation regarding proper filling of the syringe. A partially filled syringe, or short sample, results in excessive lithium concentration.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte and pH sensors.

The OPTI LION Na\(^+\) and K\(^+\) results include an appropriate correction for pH at all values of pH. This correction may introduce an extra source of variability at the extreme values.

The OPTI LION analyzer is a development of the OPTI CCA instrument and uses the same type of fluorescent sensors. Extensive testing of OPTI CCA for its 510(k) submission identified a number of interferents that were re-tested on OPTI LION. Since the dry calibration is not affected by the interferent and the wet fluorophore is the same, we do not expect new sensitivities except for the chloride sensor.

The OPTI LION Cl\(^-\) sensor exhibits an interference from the buffer species HEPES [(4-(2-hydroxyethyl)piperazine-1-ethanesulfonic acid)]. A HEPES concentration of 50 mmol/L will cause a positive Cl\(^-\) bias of 10 mmol/L.

The OPTI LION chloride sensor exhibits a small interference from tHb in whole blood measurements. A change of +10 g/dL from the mid-physiological value (13-15 g/dL) causes a chloride bias of -4 mM. A change of -10 g/dL from the mid-physiological value (13-15 g/dL) causes a chloride bias of +4 mM.

Interference testing was carried out by spiking into tonometered plasma following the CLSI guideline EP7-A2\(^8\). Spiking was carried out at CLSI recommended test levels or higher if figures were available.

---


Table of substances found to interfere with one or more of the OPTI LION measurements:

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Test level</th>
<th>pH Change</th>
<th>Na⁺ Change</th>
<th>K⁺ Change</th>
<th>Cl⁻ Change</th>
<th>iCa Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>11.5 mM</td>
<td>-0.16</td>
<td>-6 mM</td>
<td>Not significant</td>
<td>Not significant</td>
<td>+0.1mM</td>
</tr>
<tr>
<td>Sodium Salicylate</td>
<td>10 mM</td>
<td>Not significant</td>
<td>Unstable reading</td>
<td>+1.8 mM</td>
<td>+32 mM</td>
<td>+0.5 mM</td>
</tr>
<tr>
<td>Sodium Thiocyanate</td>
<td>3 mM</td>
<td>Not significant</td>
<td>+16 mM</td>
<td>Not significant</td>
<td>+12 mM</td>
<td>Not significant</td>
</tr>
<tr>
<td>Phenylacetic Acid</td>
<td>10 mM</td>
<td>-0.12 mM</td>
<td>+8 mM</td>
<td>Not significant</td>
<td>+11 mM</td>
<td>+0.14 mM</td>
</tr>
<tr>
<td>Ammonium Chloride</td>
<td>5 mM</td>
<td>Not significant</td>
<td>Not significant</td>
<td>+2.5 mM</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
<tr>
<td>Nickel Sulphate</td>
<td>0.1 mM</td>
<td>Not significant</td>
<td>Unstable reading</td>
<td>+1.1 mM</td>
<td>+27 mM</td>
<td>+0.28 mM</td>
</tr>
<tr>
<td>Fluorescein</td>
<td>25 mg/dL</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td></td>
</tr>
<tr>
<td>Cardio (indocyanine) green</td>
<td>0.5 mg/dL</td>
<td>Not significant</td>
<td>+13 mM</td>
<td>+0.4 mM</td>
<td>+11 mM</td>
<td>Not significant</td>
</tr>
<tr>
<td>Methylene Blue</td>
<td>25 mg/dL</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td>Unstable reading</td>
<td></td>
</tr>
</tbody>
</table>

Table of substances not found to interfere with the OPTI LION analyzer:

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Test level</th>
<th>pH Change</th>
<th>Na⁺ Change</th>
<th>K⁺ Change</th>
<th>Cl⁻ Change</th>
<th>iCa Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>40 mg/dL</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
<tr>
<td>Beta-Carotene</td>
<td>0.6 mg/dL</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
<tr>
<td>Copper (II) sulphate</td>
<td>0.1 mM</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
<tr>
<td>Evans Blue</td>
<td>5 mg/dL</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

Only clear, uncolored quality control materials, such as OPTI CHECK LYTES brand aqueous controls should be used with the OPTI LION system. Colored materials, including proficiency and QC testing materials, may interfere with the pH or ion measurement, or fail to be properly aspirated.
Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI LION instruments. pH is expressed in pH units and all other values in mmol/L.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>mean</th>
<th>Swr (CV%)</th>
<th>Sdd (CV%)</th>
<th>ST (CV%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material: OPTI CHECK LYTES aqueous control solution Level 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>115</td>
<td>1.1 (1.0%)</td>
<td>0.6 (0.5%)</td>
<td>1.2 (1.1%)</td>
</tr>
<tr>
<td>Potassium</td>
<td>2.9</td>
<td>0.08 (2.6%)</td>
<td>0.016 (0.8%)</td>
<td>0.09 (3%)</td>
</tr>
<tr>
<td>Chloride</td>
<td>82</td>
<td>1.8 (2.2%)</td>
<td>0.6 (0.8%)</td>
<td>2.1 (2.6%)</td>
</tr>
<tr>
<td>ionized Calcium</td>
<td>1.9</td>
<td>0.09 (4.8%)</td>
<td>0.03 (1.7%)</td>
<td>0.1 (5.5%)</td>
</tr>
<tr>
<td>pH</td>
<td>7.15</td>
<td>0.02 (0.3%)</td>
<td>0.01 (0.16%)</td>
<td>0.02 (0.03%)</td>
</tr>
<tr>
<td>Material: OPTI CHECK LYTES aqueous control solution Level 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>139</td>
<td>0.9 (0.6%)</td>
<td>0.3 (0.2%)</td>
<td>1.0 (0.7%)</td>
</tr>
<tr>
<td>Potassium</td>
<td>4.4</td>
<td>0.07 (1.6%)</td>
<td>0.06 (1.3%)</td>
<td>0.1 (2.3%)</td>
</tr>
<tr>
<td>Chloride</td>
<td>107</td>
<td>2.4 (2.3%)</td>
<td>1.2 (1.1%)</td>
<td>2.7 (2.5%)</td>
</tr>
<tr>
<td>ionized Calcium</td>
<td>1.4</td>
<td>0.04 (2.9%)</td>
<td>0.02 (1.3%)</td>
<td>0.05 (3.7%)</td>
</tr>
<tr>
<td>pH</td>
<td>7.34</td>
<td>0.02 (0.3%)</td>
<td>0.01 (0.1%)</td>
<td>0.02 (0.3%)</td>
</tr>
<tr>
<td>Material: OPTI CHECK LYTES aqueous control solution Level 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>163</td>
<td>1.0 (0.6%)</td>
<td>0.4 (0.2%)</td>
<td>1.1 (0.7)</td>
</tr>
<tr>
<td>Potassium</td>
<td>6.1</td>
<td>0.1 (1.9%)</td>
<td>0.06 (0.9%)</td>
<td>0.15 (2.4%)</td>
</tr>
<tr>
<td>Chloride</td>
<td>132</td>
<td>3.1 (2.3%)</td>
<td>1.1 (0.8%)</td>
<td>3.5 (2.7%)</td>
</tr>
<tr>
<td>ionized Calcium</td>
<td>0.7</td>
<td>0.018 (2.6%)</td>
<td>0.01 (1.5%)</td>
<td>0.018 (2.7%)</td>
</tr>
<tr>
<td>pH</td>
<td>7.6</td>
<td>0.02 (0.3%)</td>
<td>0.009 (0.1%)</td>
<td>0.02 (0.3%)</td>
</tr>
</tbody>
</table>
Linearity

Wherever possible, linearity for the OPTI LION has been established against reference materials or methods. Linearity for sodium, potassium, chloride and calcium was established against the Roche (originally AVL) 9180 electrolyte analyzers. Linearity for pH was established against a Roche (originally AVL) pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers.

Linearity for aqueous samples was established using gravimetrically prepared traceable aqueous standard solutions.

Sodium, potassium, chloride and calcium linearity for plasma or whole blood was established using spiked/diluted pooled human samples. The linearity of pH measurement in plasma or whole blood samples was established using human specimens tonometered with various CO₂ gas levels.

### Linearity in Aqueous Samples

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation Coefficient</th>
<th>Sy*x</th>
<th>Range</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium</td>
<td>0.9637</td>
<td>5.5</td>
<td>0.9997</td>
<td>0.55</td>
<td>100-194</td>
<td>26</td>
</tr>
<tr>
<td>potassium</td>
<td>0.9623</td>
<td>0.17</td>
<td>0.9988</td>
<td>0.095</td>
<td>1.0-9.6</td>
<td>26</td>
</tr>
<tr>
<td>chloride</td>
<td>1.0066</td>
<td>-2.1</td>
<td>0.9936</td>
<td>2.53</td>
<td>63-147</td>
<td>27</td>
</tr>
<tr>
<td>ionized calcium</td>
<td>0.9791</td>
<td>0.008</td>
<td>0.9863</td>
<td>0.068</td>
<td>0.3-2.0</td>
<td>26</td>
</tr>
<tr>
<td>pH</td>
<td>1.0034</td>
<td>-0.046</td>
<td>0.9976</td>
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### Linearity in Plasma Samples

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### Linearity in Whole Blood Samples

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9 Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).
Correlation to Other Methods

OPTI LION vs other pH/Electrolyte Instruments on whole blood in a typical setting

Excess blood and serum aliquots from specimens collected for blood gas or chemistry analyses were analyzed using blood gas and chemistry equipment in hospital laboratories. The blood was analyzed on the OPTI LION after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

### Comparative Method: OPTI CCA in whole blood

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### Comparative Method: OPTI CCA in Serum

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### Comparative Method: Roche OMNI in whole blood

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### Comparative Method: Roche Integra in Serum

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9. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).
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1 GETTING TO KNOW YOUR OPTI® LION ELECTROLYTE ANALYZER

1.1 Overview

1.1.1 Important Safety Instructions

Before you begin installing your OPTI® LION, carefully read the overview information in this chapter.

For your own safety and the proper operation of your equipment, always follow these precautions when working with your OPTI LION:

- Keep the analyzer away from all sources of liquids such as sinks and wash basins.
- Keep the analyzer away from explosive gases or vapors.
- Always handle blood samples and collection devices with care.
- Use approved protective gloves to avoid direct contact with sample.
- Dispose of OPTI Cassette according to local regulations.

1.1.2 Analyzer Components

The OPTI LION is a fully automatic, microprocessor-controlled medical instrument that measures Na⁺, K⁺, Cl⁻, iCa and pH using a disposable cassette.

The OPTI LION is designed to measure the above parameters in whole blood, serum/plasma and aqueous samples (OPTI CHECK LYTES and QC materials).
The analyzer has several major components which are important for you to understand (Fig. 1-1).
A backlit **VGA screen** is used to display the analyzer status, Patient and QC sample results and other relevant information. The graphic interface is a **touch screen** which is used to perform all analyzer functions (Fig. 1-2).

To the right of the touch screen is a two color **status light** (Fig. 1-3). During instrument operation the status light will indicate the following:

- **Green Light**: System is ready for measurement.
- **Blinking Green Light**: System is in process of calibration or measurement. Do not open the cover.
- **Red Light**: Major error has occurred, system has stopped.
- **Blinking Red Light**: System has encountered a problem and needs operator interaction before it will proceed.

Inside the top of the unit is the **Sample Measurement Chamber** (SMC) for the OPTI Sensor Cassette. To open the cover, press the release button. The cover will then pop up (Fig. 1-4).

Several LEDs are located inside the sample measuring chamber.
The self-contained **OPTI Sensor Cassette** contains a self-sealing sample path, allowing safe, clean sample disposal (Fig. 1-5).

**NOTE:** Store OPTI LION cassettes refrigerated from 2-8°C (35-46°F). Cassettes may be used directly out of the refrigerator. No temperature equilibration time is necessary; however, cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 2 weeks.

The **cassette fillport** projects from the measurement chamber for connection to a sample probe. The **sample probe** is attached to the fillport for sample aspiration from sample collection tubes, sample cups and syringes (Fig. 1-6).

**NOTE:** **DO NOT INJECT** the sample into the cassette. The sample is aspirated automatically.

On the right side of the instrument is the **bar code reader**. The barcode reader is used to read lot number, expiration date, and QC Ranges if applicable from cassettes, controls and SRCs, as well as user-input bar codes for operator and patient IDs (Fig. 1-7).
The **thermal printer** is accessible by raising the printer cover on the left top corner of the analyzer (Fig. 1-8). The printer uses document grade thermal printer paper to output information in 27 columns. The analyzer can print measured patient values, quality control values, calibration values, as well as diagnostic information.

Contained within the printer compartment is a **peristaltic pump** cartridge which is used to transport liquids. All liquids are contained within the OPTI Sensor Cassette and do not enter the instrument (Fig. 1-9).

*NOTE: The peristaltic pump cartridge is a replaceable item (See Maintenance Section).*

The model and serial number identifiers are located on an **identification plate** on the bottom panel of the unit (Fig. 1-10).
On the rear of the unit is (Fig. 1-11):

- An **RS232 interface port**
- An **Ethernet port**.
- A **storage compartment** that can hold an extra paper roll, the Standard Reference Cassettes, Calibration cassette and other supplies or accessories.
- A **Compact Flash Card slot (CF Slot)** for software updates or storage of patient and QC data in a .CSV file.

![Fig. 1-11 Rear of the OPTI LION](image)

On the left side of the unit is the **power connector** where the OPTI LION is connected to an external power supply (Fig. 1-12).

The **On/Off** switch is located on the left side of the unit next to the power connector (Fig. 1-12).

*NOTE: Allow a 30 second delay when switching the power ON/OFF.*

![Fig. 1-12 Power Connector and On/Off Switch](image)

**Congratulations!**

You have just learned the basic components of the analyzer and are now ready to install your system.
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2 INSTALLATION

2.1 Unpacking the OPTI® LION Electrolyte Analyzer

Location is important for trouble-free operation of your analyzer. Before you begin setup, choose a site that is convenient for your sampling needs and meets the following physical requirements of the unit:

- Grounded electrical outlet.
- Away from direct sunlight.
- Room temperature within 10 - 32° C (50 - 90° F).
- Maximum relative humidity of 95%.
- Ample room to allow air to circulate around the unit.
- Away from strong electromagnetic fields, such as those created by electric motors and X-ray equipment.
- Away from explosive gases or vapors.
- Placed on flat surface with ample room between air vents on bottom of unit and surface to prevent unit overheating.

Now it’s time to unpack your OPTI LION.

Before you begin installing your system, take a moment to look over the contents to ensure that you have everything you need to get your analyzer up and running. Check to make sure you have these supplies.

- Power Supply with Power Cord
- Quality Control Material (OPTI CHECK LYTES (HC7010))
- Printer Paper
- 2 Standard Reference Cassettes (SRCs) (Level 1 (BP7604) and Level 3 (BP7606))
- Calibration Cassette (BP7607)
2.2 Setting Up

You are now ready to prepare your OPTI LION Analyzer for operation.

Begin by placing the analyzer on a secure table top that allows plenty of working space and is convenient to a power connection.

1. Plug in the Power Supply
   - Plug the power supply into the receptacle on the left side of the unit (Fig. 2-1).
   - Plug the power cord into the power supply.
   - Plug the cord into a grounded electrical outlet.

   **NOTE**: The green LED on the power supply should be lit when plugged into the electrical outlet.

   **NOTE**: To protect your OPTI LION and other electronic devices from damage caused by electrical power spikes, OPTI Medical recommends the use of a surge protector.

2. Turn on the Power
   - Locate the power switch on the left side of the unit and switch to ON (Fig 2-2).

   - This is the first screen that will appear after the power is turned on (Fig. 2-3)

   - Press OK.
3. Setting the Time and Date

During warm-up, the system will prompt you to set the time and date.

- Enter the current time using the numeric keypad (Fig. 2-4).
- Enter hour and minutes and press OK.

- You will then be asked to enter the month (Fig. 2-5).
- Select the month from the keypad and press OK.

- In the next screen, you may enter the current day (Fig. 2-6).
- Press OK and enter the 4-digit year.
- After entering the current time and date press OK to save your settings.
As soon as the OPTI LION has completed the warm-up, the <Ready> display appears (Fig. 2-7).

4. Installing the Printer Paper

- Place paper into the paper tray.

- With the OPTI LION switched on, thread the paper into the feeder slot, as shown in the diagram, on the analyzer (Fig. 2-8).

- As soon as the printer detects the paper, it will automatically feed the paper completely through the printer. The paper advance button should only be used if paper is present.

- To advance paper after the initial installation, press the red paper advance button located on the left side of the printer (Fig. 2-9).

*NOTE: The red paper advance button is only active when the printer detects paper in the printer.*
5. QC Setup

- Set up the information for the Standard Reference Cassettes (SRC’s, Level 1 and 3) prior to initial patient testing. SRC’s are supplied with every analyzer and are located in the storage compartment of the analyzer. Refer to Chapter 3, section 3.3.1.1 “Setting up the Standard Reference Cassette” for SRC set up instructions.

- Set up the OPTI Check Lytes or other quality control material information prior to initial patient testing as well. Refer to Chapter 3, section 3.3.1.2 “Setting up the Quality Control Material Lot and Level” for quality control set up instructions.

6. Run QC Prior to Patient Testing

- Run the calibrator cassette supplied with the analyzer located in the storage compartment prior to initial patient testing. Refer to Chapter 6, section 6.3 “Quarterly Maintenance – Performing Intensity Calibration” for instructions.

- Run the Standard Reference Cassettes. Refer to Chapter 4, section 4.5.1 “Running an SRC Measurement” for instructions.

- Run at least one level of OPTI Check Lytes or other quality control material that was set up in the section above. Refer to Chapter 4, section 4.5.3.1 for instructions on running controls.

*NOTE: The OPTI LION will lock-out patient testing until one level of controls passes on a particular lot of cassettes. One control level must pass to remove the lock-out for each new lot of cassettes tested.*

*Congratulations! Your OPTI LION is now ready for use.*
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3 CUSTOMIZATION

The OPTI® LION is shipped preconfigured to easily perform sampling operations. The intuitive graphics on the color touch screen will allow you to easily enter, review and print patient, QC and SRC information, as well as easily configure your system setup to tailor the instrument’s operation to match the particular needs of your lab.

NOTE: For safety and security the OPTI LION Setup menus can be password protected. The analyzer’s setup configuration can then be changed only by entering the correct password.

NOTE: All system setup selections are saved in the instrument memory even after the system power is turned off.

3.1 Data Manager

In <Data Manager> you can print, view and delete Patient, SRC, Control and Calibration information. In this menu you can also export Patient and QC information to a connected computer or HIS/LIS. Procedures for printing information are found in Chapter 4 “Calibration and Quality Control” and Chapter 5 “Patient Testing”.

3.2 Setting Time And Date

1. In the main menu, press <System Manager> (Fig. 3-1) to access the <System> menu. Press <Time and Date> (Fig. 3-2) and the <Time and Date Settings> screen will appear (Fig. 3-3).
2. In the **System -> Time and Date** Settings screen (Fig. 3-4), press **Up** to leave the default time and date setting unchanged, or press the **Edit** button to call up a numeric keypad that can be used to change the time and date setting.

3. In **Time Format**, press the respective radio button, **12hr** or **24hr** to change the time units.

4. To change from Standard Time to Daylight Savings Time, select the option **Daylight Savings Enable**.

5. Press **Save** to accept the changes.

6. Press **Up** to return to the **System** screen or **Home** to return to **Ready**.

### 3.3 Setup

In the **Setup** menu you will be able to enter new quality control and SRC materials, configure the printed reports, set up system security and customize several other system features.

1. From the **Ready** display, press **System Manager** to access the **System** menu.

2. Press **Setup** to select this function (Fig. 3-5).

3. Enter the password 404 (factory setting) to access the setup functions.

**NOTE:** You may not be prompted to enter a password if the password was previously disabled (see Section 3.3.3.4.1).

**NOTE:** If the factory-set password was changed, enter the current valid password.
3.3.1 QC Setup

3.3.1.1 Setting Up the Standard Reference Cassette (SRC)

When you open a new SRC lot, the lot number and expiration date should be entered into the system. Each SRC level has a unique lot number printed on the pouch. To enter new SRC information, follow the instructions below.

**NOTE:** The procedure for programming SRC QC ranges as described below is identical for all levels.

1. From the <Ready> display, select <System Manager> and <Setup>.
2. Enter the password, if this security function has been activated.
3. In the <System Setup> menu, press <SRC> (Fig. 3-6).
4. Take an SRC pouch and read the cassette information into the system by “swiping” the bar code across the bar code reader located at the bottom right hand corner of the system (Fig. 3-7).
   - The bar code should face the instrument.
   - A beep indicates a valid bar code.
   - A red status light indicates an invalid bar code (e.g. SRC expired or wrong cassette type).
5. If the level, lot number and expiration date are correct, press to save the settings (Fig. 3-8).

---

**Fig. 3-6** Select SRC

**Fig. 3-7** Swipe Bar code

**Fig. 3-8** Confirm SRC Information
### Setting up the Quality Control Material Lot and Level

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>.

2. Enter the password, if this security function has been activated.

3. Select `<Control>` (Fig. 3-9).

4. Swipe the 38-digit bar code for the applicable level supplied with OPTI CHECK LYTES.

**NOTE:** If bar code is not available or unreadable, press `<Manual Entry>` on the `<Swipe Barcode>` screen and manually enter control data (Fig. 3-10).

5. Press Yes to obtain a printout of the old SRC database.

6. Press Yes to delete the old SRC database and to enter the new SRC data. If you select No, the old SRC data will remain in the database and the new SRC information will not be saved.

To continue entering SRC information, repeat the above procedure for all levels of SRCs.
3.3.1.2.1 Entering Control Expiration Date, Type, and Assay Ranges

When you open a new box of OPTI CHECK LYTES or another recommended product, the lot number, expiration date and target ranges should be entered into the analyzer. Each level of quality control material has its lot number and expiration information printed on the insert sheet within the control box.

**NOTE:** OPTI CHECK LYTES Quality Control materials are designed for your OPTI LION and have assigned target ranges for each measured parameter. Do not use control materials that contain dyes, fluoro-carbons or silicones as these constituents will affect the results reported.

**NOTE:** The procedure for programming QC information as described below is identical for all levels.

1. From the previous bar code entry, confirm lot number, expiration date and control type on the package insert supplied with the control material (Fig. 3-11).

2. Press to accept.

3. Press to obtain a printout of the old QC information stored in the database.

4. Press to delete the old database.

**NOTE:** The OPTI LION can only store one lot of QC information per level at one time. In order to enter a new lot of QC information, the OLD lot must be deleted.

**NOTE:** If no previous QC data exists in the database, the print and delete display screens will be bypassed.

**NOTE:** If you do not want to change the current lot information, but want to verify current programmed QC ranges, press <NO> for both of the above options.
5. Press the <Ranges> tab to confirm the QC target ranges on the package insert supplied with the control material (Fig. 3-12).
You can also manually enter the QC ranges by pressing the Edit button and entering the
values using the keypad. Enter 0.0 for parameters for which you will not need QC range assignments.

6. Press Save to save settings.

**NOTE:** You will find the QC target ranges printed on the insert sheet in the box of control material. Alternately you may develop your own target ranges from multiple measurements according to your hospital’s procedures.

**NOTE:** Although it is recommended you review all analyte target ranges, you may press Save at any time after the bar code is swiped, and the ranges will be accepted from the bar code.

To continue quality control programming, repeat the above procedure for the remaining QC levels.
### 3.3.1.3 Setting the Printer

The `<Printer>` menu is used to program the printer settings.

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>.
2. Enter the password, if this security function has been activated.
3. In the `<System Setup>` menu, press `<Printer>` (Fig. 3-13).

In the `<Printer>` screen (Fig. 3-14), you can select to have a patient report printed at the end of each measurement (default - enabled).
You can also select to have the cassette calibration report printed with each patient report (default - disabled).
The next option lets you add reference ranges to each patient report.
After selecting the desired reports, you can select the number of copies to be printed (default - 1).
4. Select the options to be enabled.
5. Press `Save` to save settings.
6. Press `Up` or `Home` to return to the `<Setup>` screen or to return to the `<Ready>` screen.

**NOTE:** This setting only affects the patient reports. All other print functions are still active, even if the patient report is not activated.
### 3.3.2 Customizing Patient Information

#### 3.3.2.1 Selecting Which Patient Information is Requested and Printed

In the `<Patient Entry>` menu you can configure which patient input is available during, as well as printed after, each measurement.

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>`.
2. Enter the password, if this security function has been activated.
3. In the `<System Setup>` menu, press `<Patient Entry>` (Fig. 3-15).
4. In the `<Patient Information>` screen, select the options to be enabled (Fig. 3-16).

   - **Patient ID**: (default enabled, optional)
   - **Operator ID**: (default enabled, optional)
   - **Accession #:** (default enabled, optional)

   **NOTE:** If a selection is `REQUIRED`, the user must enter the requested information during sample measurement.

5. Select `<Optional>` or `<Required>` for:
   - **Patient ID**
   - **Operator ID**
   - **Accession #**

6. Other options that can be selected are:
   - **Sample Type**
   - **Temperature**
   - **Sex**
   - **DOB**
   - **User Defined Field**

7. Press **Save** to save settings.
8. Press **Up** to return to the `<Setup>` screen or **Home** to return to `<Ready>`.
3.3.2.2 Selecting Which Parameters Are Blanked/Disabled

In the <Measured Parameters> menu you can enable parameter blanking and disable certain parameters from being reported on the analyzer.

1. From the <Ready> display, select <System Manager> and <Setup>.

2. Enter the password, if this security function has been activated.

3. In the <System Setup> menu, press <Measured Parameters> (Fig. 3-17).

4. Press <Allow Blanking> to allow parameter blanking (Fig. 3-18).

   If blanking is enabled, the user is prompted to choose which measured parameter will be disabled or removed from the record after each patient sample measurement. If for example, Cl is disabled, this result will not appear in the stored patient results or on the printout.

5. The next option, <Reported Parameters>, allows you to permanently disable the selected parameters from all patient sample and QC measurements.

6. Press to save settings.

7. Press to return to the <Setup> screen or to return to <Ready>.
### Selecting Which Calculated Parameters Are Printed

Select the `<Calculated Parameters>` menu to enable specific calculated parameters to be reported on patient samples.

**NOTE:** The display will always let you view all available calculated parameters.

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>`.
2. Enter the password, if this security function has been activated.
3. In the `<System Setup>` menu, press `<Calculated Parameters>` (Fig. 3-19).
4. Select the cassette type (Fig. 3-20).

**NOTE:** The calculated parameters will only be enabled for the cassette type selected.
5. Select the calculated parameters to be enabled for patient samples.
6. Press ![Save](image) to save settings.
7. Press ![Up](image) to return to the `<Setup>` screen or ![Home](image) to return to `<Ready>`.

---

**Fig. 3-19** Select Calculated Parameters

![System>Setup>Calculated Parameters](image)

**Fig. 3-20** Select Parameter
3.3.3 Miscellaneous

3.3.3.1 Setting Normal Ranges or Alarm Limits

The Normal Ranges/Alarm Ranges menu is for selecting the range limit “name” as it appears on the printout and to configure the parameter alarm limit values. These limit names can be based on your hospital policy and may be selected from the following: “Reference”, “Normal”, “Physiologic”, “Alarm” or “Critical”.

Results that are outside the defined limits will be flagged with an up-arrow if high, or down-arrow if low. A message is included on the printout explaining each flag, using the name selected here.

NOTE: When the patient temperature has been changed, both the measured and temperature-corrected parameters will be checked against the programmed limit values and flagged accordingly.

1. From the <Ready> display, select <System Manager> and <Setup>.

2. Enter the password, if this security function has been activated.

3. In the <System Setup> menu, in the <Miscellaneous> section, press <Normal Ranges/Alarm Limits> (Fig. 3-21).

4. On the <Range Names> tab, select the limits range name you wish to use (Fig. 3-22):
   - Reference
   - Normal
   - Physiologic
   - Alarm
   - Critical
5. Press <Limits> to advance to the next screen (Fig. 3-23) and press <Edit> to enter the new limit value for each parameter.

6. Press <Save> to save the new limit value.

The instrument is preset to the following limit values:

- Na\(^+\): 135 - 145 mmol/L
- K\(^+\): 3.5 - 5.1 mmol/L
- Cl\(^-\): 95 - 115 mmol/L
- iCa: 1.12 - 1.32 mmol/L
- pH: 7.2 - 7.6

**NOTE:** Units may be changed (See section 3.3.3.3).

**NOTE:** If out-of-range values are entered, the system will automatically flag the error and display the valid range.

**NOTE:** Do not use flagged results for treatment - repeat the sample measurement.

**NOTE:** If you wish to turn off limits flagging, enter the reportable measurement range for each parameter. For instance, the reportable range for pH is 6.600 (low) and 7.800 (high) (See method sheet for the reportable measurement range for each measured parameter).

**NOTE:** The limits will reside in the instrument memory even after system power is turned off.

7. Press <Up> to return to the <Setup> screen or <Home> to return to <Ready>. 

---

Fig. 3-23 Enter Limits
3.3.3.2 Setting up Correlation Factors

The <Correlation> menu is used to enter calculated slope and offset correlation factors that allow you to correlate the OPTI LION results with another electrolyte analyzer. Correlation factors are available for Na⁺, K⁺, Cl⁻, iCa and pH.

NOTE: Slope is a multiplicative factor and Offset is an additive factor, using the following formula:

Correlated value = Raw value * slope + offset.

1. From the <Ready> display, select <System Manager> and <Setup>.
2. Enter the password, if this security function has been activated.
3. In the <System Setup> menu, press <Correlation> (Fig. 3-24).
4. Select the values to be entered by pressing <Edit> (Fig. 3-25). Enter the new values.
5. When entering the actual offset value, select whether it is a positive or negative value using the +/- keys.

NOTE: The factory default setting is 1.000 for all slopes and 0.000 for the offsets. These essentially deactivate the correlation factors.

6. Enter the correlation factors for remaining parameters as described above.
7. Press <Save> to accept the changes.
8. Press <Up> or <Home> to return to the <Setup> screen or <Ready>.

NOTE: Altering the correlation factors will alter your measurement results. Be very careful to enter the correct values and confirm the settings by running at least 10 comparison measurements between the OPTI LION and the instrument to which it is to be correlated.
3.3.3.3 Defining Units

The <Units> menu is used to select the units of measure for temperature, iCa and resolution.

1. From the <Ready> display, select <System Manager> and <Setup>.

2. Enter the password, if this security function has been activated.

3. In the <System Setup> menu, press <Units> (Fig. 3-26).

4. In the <Units> screen, select the units for the displayed parameters (Fig. 3-27).

5. Select <Resolution> High or Low to determine the number of digits displayed and printed past the decimal point, for all measured parameters.

   **NOTE:** The selection applies to sample results only. Resolution is always High for Quality Control, SRC results and calculations. Resolution examples are shown in the following table:

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺ 143 mmol/L</td>
<td>Na⁺ 143.3 mmol/L</td>
</tr>
<tr>
<td>K⁺ 4.6 mmol/L</td>
<td>K⁺ 4.57 mmol/L</td>
</tr>
<tr>
<td>Cl⁻ 103 mmol/L</td>
<td>Cl⁻ 103.1 mmol/L</td>
</tr>
<tr>
<td>iCa 1.21 mmol/L</td>
<td>iCa 1.21 mmol/L</td>
</tr>
<tr>
<td>pH 7.34</td>
<td>pH 7.341</td>
</tr>
</tbody>
</table>

   The OPTI LION is configured with the following default units:

   - Temperature: °C
   - iCa mmol/L
   - Resolution Low

   **NOTE:** The OPTI LION automatically recalculates the units stored in the database to the changed unit value.

6. Press eSave to save settings.

7. Press eUp to return to the <Setup> screen or eHome to return to <Ready>.
3.3.3.4 Setting up Security

The `<Security>` menu is used to configure the following OPTI LION security settings:

- **Setup Password**: A password function to limit access to various system setup functions (See section 3.3.3.4.1).
- **QC Lockouts**: An automatic QC scheduler to help hospitals meet their QC policies (See section 3.3.3.4.2).
- **Operator ID and password (PIN)**: Limits analyzer access to authorized users (See section 3.3.3.4.3).

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>`.
2. Enter the password, if this security function has been activated.
3. In the `<System Setup>` menu, press `<Security>` (Fig. 3-28).

3.3.3.4.1 Setting Up a Password

When the password is enabled, the access to the setup menus and certain database functions will only be granted when the password is entered. The password function ensures that only authorized operators can alter customized settings. The factory default password is 404. The factory-set password can be changed to any number between 0 and 9999 (up to 4 digits).

1. Select `<Password Enable>` in the `<Security>` menu (Fig. 3-29). Enter a numeric password (up to 4 digits) in the `<Setup PW>` field.
2. Press `Edit` to enter the numbers and press `Save` to save the settings.
3.3.3.4.2 Selecting QC Lockout

The <QC Lockout> menu is used to configure the SRC and QC schedule regarding number of levels and time interval. When this option is selected, the operation of the OPTI LION is ‘locked-out’, unless QC has been run according to its settings. Each facility should develop their own policies on the frequency and type of QC based on the regulatory requirements. The instrument is factory-set with lockout options turned off.

To activate these options:

- Select <QC Lockout> in the <Security> menu (Fig. 3-30).

**Option 1:**

- <SRC Lockout Enable> - Select the number of SRCs that should be run in an interval: one, two or three levels. If the selected number of SRCs is not run within the interval, patient measurements will not be allowed. Next, select the time interval at which SRCs should be run:
  - <8hr> - every 8 hours.
  - <12hr> - every 12 hours.
  - <24hr> - every 24 hours.
  - <7dy> - every 7 days.

- Press to save settings.

- Press to return to the <Setup> screen or to return to <Ready>.

**NOTE:** The time interval start time begins with the time this feature is activated.
Option 2:

<Control Lockout Enable> - Select the number of liquid QCs that should be run in an interval: one, two or three levels. If the selected number of QCs is not run within the interval, patient measurements will not be allowed. Next select the time interval at which QCs should be run:

<8hr> - every 8 hours.
<12hr> - every 12 hours.
<24hr> - every 24 hours.
<1mo> - every month.
<2mo> - every 2 months.

- Press \( \text{Save} \) to save settings.
- Press \( \uparrow \) to return to the <Setup> screen or \( \text{Home} \) to return to <Ready>.

**NOTE:** More than one option can be selected. For instance, laboratories can require that a combination of SRCs and liquid QC is run on a daily basis. This should be based on hospital policy.
3.3.3.4.3 Setting up Secure Operator IDs

The <OP IDs> menu is used to enter Operator identification IDs and password (PIN). With this feature enabled, the system will “lock out” unauthorized users from operating the analyzer.

- Select <OP IDs> in the <Security> menu (Fig. 3-31).
- Select <Secure Operator ID Enable>.

**NOTE:** If you do not select this option, the <Secure Op IDs> feature is turned off, and operators will not be required to enter their PIN numbers to operate the analyzer.

1. Press the button to enter the Operator ID number (up to 11 digits) and a unique 4-digit personal identification number (PIN) to be added to the list of authorized users.

   The analyzer can store up to 300 Operator IDs and associated PINs.

   **NOTE:** The 4-digit PIN must be unique and will be required by the operator to access analyzer functions. The Operator ID number will be printed on all reports associated with their PIN.

   OR

2. Select an Operator ID number to be deleted from the list of valid users currently stored in memory, and press the button to remove the operator ID from memory.

   OR

3. Press the button to print the list of all operator IDs, along with their associated PINs, as currently stored in memory.

4. Press the button to return to <Ready>.
### 3.3.3.5 Beep Adjustment

The `<Hardware>` menu is used to adjust audible alarm, communication and standby settings. To adjust the audible alarm, follow the instructions below:

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>`.
2. Enter the password, if this security function has been activated.
3. In the `<System Setup>` menu, press `<Hardware>`.
4. In the `<Hardware>` screen, select `<Beep Enable>` (Fig. 3-32).
5. Select `<High>` or `<Low>` for `<Beep Volume>`.
6. Press to save settings.
7. Press to return to the `<Setup>` screen or to return to `<Ready>`.

![Fig. 3-32 Enable Beep](image)
3.3.3.6 Setting Up Communications

The OPTI LION has an RS232 standard serial interface with a baud rate fixed at 9600 and a CF port. The serial port may be configured for ASCII or ASTM output.

3.3.3.6.1 Configuring the Communication Format

1. From the <Ready> display, select <System Manager> and <Setup>.
2. Enter the password, if this security function has been activated.
3. In the <System Setup> menu, press <Hardware>.
4. In the <Hardware> screen, select <Communication Format>: <ASCII>, <ASTM> or <CF> (Fig. 3-33).
   - <ASCII Format> - The OPTI LION exports a data string identical to the internal printer output.
   - <ASTM Format> - Complies with ASTM standard with handshaking and data formatting.
   - NOTE: ASTM Format is recommended for use with stationary RS232 operation.
   - <CF Format> - Compact Flash is used for archiving data to a Compact Flash Card. An Export Kit is available (BP7140) with a properly formatted card, instructions and card reader. By selecting comma or semicolon, data can be easily exported into a PC.
5. Press to save settings.
6. Press to return to the <Setup> screen or to return to <Ready>. 
3.3.3.7 Backlight Auto-Off Mode

In this menu you can enable the automatic backlight function. When this function is enabled, the backlight of the display will turn off automatically at the selected time interval.

1. From the <Ready> display, select <System Manager> and <Setup>.

2. In the <System Setup> menu, press <Hardware>.

3. In the <System->Setup->Hardware> screen, select <OFF>, <10 Min> or <60 Min> time intervals for the backlight auto off feature (Fig. 3-34).

4. Press to accept the changes.

5. Press to return to the <Setup> screen or to return to <Ready>.
### 3.3.3.8 Selecting a Language

This menu lets you choose the language you want the OPTI LION to use for displays and printouts.

1. From the `<Ready>` display, select `<System Manager>` and `<Setup>`.
2. In the `<System Setup>` menu, press `<Language>` (Fig. 3-35).
3. Select the desired language (Fig. 3-36).
4. Press ![Save](image) to accept the changes.
5. Press ![Up](image) to return to the `<Setup>` screen or ![Home](image) to return to `<Ready>`.

**NOTE:** If your system’s language has been altered and you are unable to find this menu to change it back, call OPTI Medical Technical Support.
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4 CALIBRATION AND QUALITY CONTROL

4.1 Calibration

Each lot of OPTI® LION cassettes is calibrated during the manufacturing process. The calibration is performed to determine the cassette’s measurement characteristics at multiple points within the analyte’s measurable range. Every cassette package is then labeled with a bar code containing this calibration information, as well as its lot number and expiration date.

Prior to running a sample, the cassette’s bar code is read into the analyzer by ‘swiping’ the cassette package through a conveniently located bar code reader. The cassette is then installed and a calibration verification is performed by reading the dry sensors. If the sensors have 0% humidity, they have a high intensity which allows referencing back to the factory 2-point calibration. In addition, an optical zero point calibration of all optical channels is performed.

During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, temperature control, proper equilibrium behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of dirty optics, or worn pump conditions.

An intensity calibration of the measurement LEDs is required every 3 months. This calibration is performed using the Calibration Cassette. The calibration verifies the measurement LEDs and electronics and corrects any potential drift.

For more information, including detailed instructions, on the intensity calibration, see Section 6.3 “Quarterly Maintenance” in this manual.

4.2 QC Overview

The intent of a Quality Control program is to assure reliable patient values over the clinically significant ranges for all the measured parameters. The program should involve the total process of specimen collection, preparation and results analysis, reporting and interpretation, and the training of personnel involved in all of these processes.

A Quality Control program for pH and electrolyte analysis includes the analysis of materials with known values or ranges of expected values and the comparisons of the results from the analyzer with these values. This program allows the analytic performance of a laboratory to be evaluated and documented.
An effective Quality Control program should include:

- evaluation of precision over the entire analytical range
- an assessment of failure modes and their effects and means of management, throughout the process
- simple statistical calculations which provide a means of assessing precision
- control charts or graphs which contain warning limits to assist the technical staff in the evaluation of results
- a clear set of guidelines to assist the staff in determining if patient results are acceptable
- a clear set of corrective actions to be taken in “out-of-control” situations

### 4.3 Proficiency Testing

Proficiency testing complements the above Quality Control program and has become an integral part of a complete laboratory Quality Assurance program. The analysis of unknown samples demonstrates that your results are unbiased by previous experience and these samples more closely reflect the testing of patient samples. Proficiency testing may also serve to expand your Quality Control testing by providing samples with different levels of analytes than those measured in the daily testing program.

The relative testing performance of each laboratory participating in the proficiency survey is determined by comparing test results obtained from a significantly large group of laboratories using the same or similar instrumentation.

**CAUTION:** For the OPTI LION, please use proficiency material that is clear. Do not use material that contains dyes or emulsions.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published a protocol for establishing a quality assurance program. The Health Care Financing Administration (HCFA) and the Clinical and Laboratory Standards Institute (CLSI formerly NCCLS) have published standards for quality assurance in medical laboratories.

### 4.4 Calibration Verification

Calibration verification allows for the validation of the electrolyte analyzer’s ability to recover known values at various points within the reportable range of all parameters and may be required by various regulatory agencies.

The OPTI LION Method Sheet, included in the front section of this manual, provides precision and recovery data for all the measured parameters in the ranges that are usually encountered in the diagnostic testing of patients.

Should a laboratory wish to perform a calibration verification for measurement values outside the broad range, OPTI Medical Systems suggests correlation against flame photometry for electrolytes, and blood pH correlation with conventional blood gas analyzers.
4.5 QC Recommendations

Two Standard Reference Cassettes (SRC) should be used as a control for the OPTI LION. OPTI Medical Systems recommends that the SRC measurement be confirmed within acceptable ranges on both the high and low once each day of OPTI LION operation. These special test cassettes contain a stable optical sensor simulator which is measured by the device in exactly the same manner as any other cassette and provides assurance that all measured parameters by the device are consistent. The results obtained should fall within limits supplied with the SRCs.

NOTE: Hospitals should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency under which they operate.

On initial use of each lot of cassettes, one level of liquid QC must be run using OPTI Medical electrolyte controls (OPTI CHECK LYTES - HC7010) or equivalent material recommended by OPTI Medical Systems. At 2 month intervals thereafter, an additional QC measurement should be performed to validate the lot. These measurements should provide target values for Na⁺, K⁺, Cl⁻, iCa and pH over a range of measurement values typically seen in each laboratory. The results obtained should fall within limits defined by the day-to-day variability as measured in the user’s laboratory facility.

OPTI Medical Systems recommends the use of a noncolored pH/electrolyte control for routine evaluation of imprecision as a part of an effective quality control program.

4.5.1 Running an SRC Measurement

1. From the <Ready> display, select <QC Manager>.
2. Select <SRC> (Fig. 4-1).
3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-2).

To bypass this function, press \textbf{OK}.

\textit{NOTE: If Operator ID is configured as “required” in Setup, you cannot go to the next step unless a valid Op. ID is entered.}

\textit{NOTE: If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.}

\textit{NOTE: Bar coded Operator IDs may be entered by using the bar code reader.}

4. Open the sample chamber cover by pressing the release button (Fig. 4-3).

5. Examine the SRC to ensure it is clean and insert it into the chamber. Press down to properly seat the SRC (Fig. 4-4).
6. Close the sample chamber cover (Fig. 4-5).

After the cover has been closed, the instrument will automatically detect which level of SRC has been inserted and prompt you to verify the lot number and level (Fig. 4-6). This information can be found on both the SRC cassette itself and its storage pouch.

If the information shown on the display is correct, press Yes to continue.

If this information is incorrect, press No to interrupt this sequence and return to <QC Manager>. (See Section 3.3.1.1, “Setting up the Standard Reference Cassette (SRC)).

After you have verified that the SRC information is correct, the instrument begins the measurement process which is indicated on the display screen (Fig. 4-7). During this time (about 60 seconds), a progress bar is displayed.
7. When the measurement is complete, the unit displays the results (Fig. 4-8).
   - The unit automatically checks the results against the ranges and stores the results in its internal database.
   - For parameters within range, **<Pass>** will be displayed and printed.
   - For parameters out of range, or if an internal drift is detected, **<Fail>** will be displayed.

8. Open the sample chamber cover and remove the SRC.

9. Place the SRC back into its pouch immediately after removal from the instrument.

10. Close the sample chamber cover.
   - If the SRC test failed, gently clean the SRC, the optics window, and the inside cover of the SMC and repeat this process. If it fails again, refer to the troubleshooting section of this manual.
   - Perform the second SRC measurement with another SRC Level in the same manner. If both SRC tests passed, the unit is ready to perform measurements.

**NOTE:** For application of QC Lockout, please refer to section 3.3.3.4.2.

**NOTE:** Verify with your particular regulatory agency and your internal policy regarding number of levels and frequency of SRCs to be run. A third level (normal range) of SRC is available as an option (Part Number BP7605).
4.5.2 Printing SRC Results

This menu allows you to print out SRC reports or SRC statistical information.

1. From the <Ready> display, select <Data Manager>.
2. Select <SRC> (Fig. 4-9).
3. In the <Data - SRC Measurement> screen (Fig. 4-10), press the View button to display the SRC results (Fig. 4-11). Use the Up and Down buttons to display the previous or next page of results.
4. To print individual results, highlight the desired measurement (Fig. 4-10). To print groups of results, highlight the first measurement to be printed, press Mark, then select the last measurement to be printed. All the measurements in between will be selected.

Press All to select all results.

5. Press Print to print your selection.

6. Press the <Statistics> button to select the level(s) from which the statistics will be printed.
7. After printout, the database can be deleted by pressing Delete.

8. If a password has been activated under <Setup>, you must enter it at this time before the data is deleted.

The unit will now delete all SRC data from the internal database.

9. Press Home to return to the <Ready> display.
4.5.3 Running a QC Sample

Policies regarding the measurement of QC samples are at the discretion of the individual hospital. OPTI Medical Systems recommends that QC solutions be run, as a minimum, with each new lot number of cassettes and at two month intervals thereafter.

You should use only OPTI Medical recommended controls such as OPTI CHECK LYTES which do **NOT** contain dye or other colored material. Whenever a new lot of controls is opened, be sure to enter the lot number information into the analyzer as described in Chapter 3 “Customization”.

*NOTE: Store controls at temperature recommended by the manufacturer*

The control material should provide target values for all measured parameters over a range of measurement values typically seen in a laboratory. The results obtained should fall within limits established by the user’s laboratory.

4.5.3.1 Running Controls (OPTI CHECK LYTES)

1. In the *<Ready>* display, press *<QC Manager>*.
2. Select *<Control>* (Fig. 4-12).

![Fig. 4-12 Select Control](image)
3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-13).

To bypass this function, press OK.

**NOTE:** If Operator ID is configured as “required” in Setup, you cannot go to the next step until a Op. ID number is entered.

**NOTE:** If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.

**NOTE:** Bar-coded Operator IDs may be entered using the bar code reader.

4. Select the desired level (Fig. 4-14) and press OK.

5. Press Yes if the lot number is correct (Fig. 4-15).

**NOTE:** If a new lot number of QC material is entered, make sure the ranges have been entered into the system prior to running a sample. (See Chapter 3, Customization). If the password function is enabled, you will be asked for it before deleting the database for the old lot number.
6. Swipe the bar coded strip on the OPTI LION Cassette package past the bar code reader on the right hand side of the analyzer to automatically record the lot and calibration information for the specific cassette (Fig. 4-16). The unit will beep and the status light will turn green to confirm a valid bar code. In the case of an expired cassette, the light will turn red.

**NOTE:** If the bar code is damaged or unreadable, press <Manual Entry> and enter the bar code digits printed on the bar code label using the numeric keypad.

**NOTE:** A control measurement may be made using any cassette lot or cassette type.

7. Open the sample chamber cover by pressing the release button (Fig. 4-17).

8. Tear open the cassette pouch being careful not to tear the bar code.

**NOTE:** The cassette must be used within 1 minute of opening the pouch.

9. Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 4-18).
10. Close the SMC cover (Fig. 4-19).

11. The system starts to calibrate (Fig. 4-20). The green status light is now lit, indicating that a calibration is occurring and that the sample chamber cover should not be opened.

12. Attach the sample probe to the cassette fillport (Fig. 4-20).

**NOTE:** The sample probe must always be attached to the cassette at a 45° downward angle.

**NOTE:** If the sample measurement chamber cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.

13. When calibration is complete, it is time to place a sample (Fig. 4-21).

- Remove an ampoule from the box of controls and shake gently, being careful not to heat it with your hands.
- Gently tap the head of the ampoule with your fingernail to remove any liquid.
- Carefully open the ampoule by breaking off the top.

**NOTE:** Protect your fingers by using gloves or tissue while breaking ampoule.
4-12

Operator’s Manual – OPTI LION Electrolyte Analyzer

• For direct aspiration place the sample probe in the ampoule. You may also use a syringe to withdraw a small amount of control material from the ampoule for aspiration.

NOTE: Best results are obtained from direct aspiration from the ampoule via the sample probe. To accomplish this, place the sample probe directly into the ampoule during aspiration (Fig. 4-22). It is recommended to use a new ampoule of control material for each analyzer.

NOTE: If a syringe is used, verify that the sample probe can be easily inserted into the syringe. A tight fit can cause vacuum or bubbles and failed aspiration.

NOTE: If a syringe is used, withdraw the ampoule contents slowly to minimize agitation and do not allow bubbles to move through the syringe.

14. Insert the sample probe into the syringe (Fig. 4-23).

15. Once the sample is drawn into the sample probe the analyzer will prompt you to remove the sample and press OK (Fig. 4-24).

NOTE: Remove the sample vial or syringe carefully to avoid splatter.

NOTE: Always use PPE (Personal Protective Equipment) and observe laboratory safety guidelines.

The sample will then be drawn into the cassette for measurement (Fig. 4-25).

At this time the status light begins flashing green indicating that the cover should not be opened.
Upon completion of the measurement, the results are displayed (Fig. 4-26).

**NOTE:** The OPTI LION Electrolyte Analyzer will indicate whether the values are within or outside the programmed ranges with a <Pass/Fail> display next to the parameter label.

16. Press \( \text{Up} \) to go to the next screen (Fig. 4-27), which gives you the option to accept, reject or review the results.

- Press <Accept> if results are acceptable, and the results will be stored in the Control Database.
- Select <Reject> to reject the results. Rejected results will not be stored in the Control Database.
- Select <Review> to view the results again.

**NOTE:** In either case, the results will be printed when the data input is complete. Please follow the regulatory guidelines of your hospital for documenting corrective action, if results are rejected.

**NOTE:** If any of the results are outside of the OPTI LION's measurement range, giving a ‘LOW’ or ‘HIGH’, the results cannot be accepted to the controls database. In this case, the QC measurement should be repeated.

17. Open the sample chamber cover and remove the cassette (Fig. 4-28).

- If other levels of controls are to be run, repeat the procedure.
### 4.5.4 Printing Control Reports

Your OPTI LION can print reports containing information on the mean, Standard Deviation (SD) and Coefficient of Variation (CV) of stored QC data.

1. In the **<Ready>** display, select **<Data Manager>**.
2. Press **<Controls>** (Fig. 4-29).
3. In the **<Data - Control Measurement>** screen (Fig. 4-30), press the **View** button to display the Control results (Fig. 4-31). Use the **Up** and **Down** buttons to display the previous or next page of results.
4. To print individual results, highlight the desired measurement (Fig. 4-30). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
5. Press **Print** to print your selection.
6. Press the **<Statistics>** button to select the level(s) from which the statistics will be printed.
7. After printout, the database can be deleted by pressing **Delete**.
8. Before the database is deleted, enter the password to initiate the procedure, if a password has been activated under **<Setup>**.
9. Press **Home** to return to the **<Ready>** display.
4.5.5 Sending Data to a Computer

The OPTI LION provides you with the ability to export Patient and QC information to a connected computer or HIS/LIS.

NOTE: Prior to sending data to a computer the OPTI LION communication port must be configured (See section 3.3.3.7) and a physical connection to the receiving computer must be made.

NOTE: An optional cable (Part Number BK7002) is required to export information from the OPTI LION when utilizing the RS232 port.

NOTE: Before exporting to the Compact Flash (CF) Card (included in CF Export Kit BP7140), make sure that the Compact Flash card is properly inserted in the CF port.

1. In the <Ready> display, select <Data Manager>.
2. Select <Patient>, <SRC> or <Controls> (Fig. 4-32).
3. Select the data to be exported and press [Export] to start the data transfer (Fig. 4-33).

A warning will be displayed asking you to confirm your choice (Fig. 4-34).
If the password has been activated under <Setup>, you will be asked to enter the password to initiate the procedure.

4. Use the numeric keypad to enter the password (Fig. 4-35).
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5 \hspace{1em} \textbf{PATIENT TESTING}

The OPTI\textsuperscript{\textregistered} LION Electrolyte Analyzer provides fast and convenient measurement of Na\textsuperscript{+}, K\textsuperscript{+}, Cl\textsuperscript{−}, iCa and pH in whole blood, serum and plasma.

The analyzer will accept specimens directly from most sample collection tubes, sample cups and syringes, using a sample probe attached to the fillport of the OPTI LION Sensor Cassette.

When using a new lot of cassettes for the first time, a liquid QC measurement must be performed. The instrument will not allow a patient measurement with a new lot until this QC measurement has been performed.

\hspace{1em} \textit{NOTE: Always follow proper safety procedures when handling biological samples.}

5.1 \hspace{1em} \textbf{Sample Preparation}

5.1.1 \hspace{1em} \textbf{Whole Blood Samples}

Collect blood in a sample collection tube, sample cup or heparinized syringe. Whole blood samples should be analyzed as soon as possible, ideally within 5 minutes after collecting the sample. For brief storage of up to one hour, the sample should be iced.

\hspace{1em} \textit{NOTE: Whole blood samples require the proper amount of anticoagulant to prevent the sample from clotting. DO NOT use anticoagulants such as EDTA, citrate, oxalate, etc. Use only heparin salts as anticoagulants.}
5.2 Running A Patient Sample

(Whole Blood, Serum and Plasma)

The OPTI LION Electrolyte Analyzer is fast and easy to operate. Whenever <Ready> appears on the display, the unit is ready for sample measurement.

1. Turn on the OPTI LION and wait until the <Ready> display appears (Fig. 5-1).

2. Take a sensor cassette pouch and read the cassette information into the system by ‘swiping’ the bar code across the bar code reader located at the bottom right hand corner of the system (Fig. 5-2).
   - The bar code should face the instrument.
   - A beep and a green status light indicates a valid bar code.
   - A red status light indicates an invalid bar code (e.g. cassette expired, SRC cassette barcode, etc.).
   Read the message on the analyzer display for detailed information (See Chapter 7, Troubleshooting).

   NOTE: If the bar code is damaged or unreadable, press <Manual Entry> and enter the bar code digits using the numeric keypad.

3. Press the cover release button to open the Sample Measurement Chamber (SMC) (Fig. 5-3).

   NOTE: If using the same lot number of cassette as the previous patient sample, the cassette information may be recalled by pressing the <Last Entry> button in the <Ready> screen. The analyzer will then identify the lot number, and prompt you to open the cover, insert the cassette and close the cover.
4. Enter your Operator ID or four (4) digit PIN # if requested (Fig. 5-4).

5. Insert the cassette as follows:
   - Open the OPTI LION Sensor Cassette packet and remove the cassette and sample probe from the pouch (Fig. 5-5).
   - Insert the cassette in the SMC chamber. Press down to ensure the cassette is properly seated (Fig. 5-5).

   **NOTE:** The cassette must be used within 1 minute of opening the pouch.

   - Close the SMC cover by pressing it down firmly (Fig 5-6).
   - The green status light starts to blink indicating that the SMC cover should not be opened during this time.

   **NOTE:** If the SMC cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.
6. The system will now check the integrity of the cassette and then calibrate (Fig. 5-7). (For more information about calibration, please refer to Chapter 4 “Calibration and Quality Control”).

**NOTE:** The OPTI LION will hold calibration for 10 minutes. After this time elapses a message will be displayed to discard the cassette.

7. During the cassette calibration, firmly insert the shorter end of the sample probe into the cassette fill port (Fig. 5-7). The sample probe should be facing downward towards the recess of the instrument body.

8. After the successful calibration, the status light will stop blinking, and the display will prompt you to mix and place the sample (Fig. 5-8).
   - Mix the syringe sample well by rolling it between the palms of your hands and inverting end over end.
   - Attach the syringe to the sample probe (Fig. 5-8) and press to start the aspiration process.

**WARNING:** Do not inject the sample! It will be automatically aspirated.

9. When using a sample collection tube or sample cup, place the sample probe in the sample container (Fig. 5-8) and press . The sample is then aspirated.

10. Once the sample has been aspirated to the first cassette sensor, a display will appear asking the operator to remove the sample from the sample probe (Fig. 5-9). Remove the sample and press . The analyzer will then move the sample from the sample probe into the cassette for measurement.

**NOTE:** Remove the sample vial or syringe carefully to avoid splatter.

**NOTE:** Always use PPE (Personal Protective Equipment) and observe laboratory safety guidelines.
Next the sample is measured. During the measurement, the status light is blinking and a progress bar is displayed (Fig. 5-10).

Do not open the cover of the sample measurement chamber during the measurement. If you do, the cassette and sample must be discarded.

11. To enter patient information, press <Patient Info> (Fig. 5-11).

12. The first patient data entry screen contains the following information (Fig. 5-12):
   - Operator ID (11 characters)
   - Patient ID (15 characters)
   - Accession Number (12 characters)
   - Date of Birth
   - Temperature
   - Sample Type (Serum, Blood or Plasma)

13. To enter patient data, press Edit. Use the alphanumeric keypad to type in the desired information.

   Press OK to save the information entered.
14. Pressing the **Patient Data 2** tab will access the second patient data entry screen (Fig. 5-13):
   - User Field 1 (9 characters)
   - User Field 2 (9 characters)
   - User Field 3 (9 characters)
   - Blanking*
   - Sex (? (other), male or female)

   * NOTE: Parameter blanking will omit a parameter from the printout (See Section 3.3.2.2 for detailed description).

   **NOTE:** The above list is configurable in the instrument setup menu (See Section 3.3.2.1). It is not necessary to enter all of the above parameters. You can press ![Home](home) at any time to exit the menu.

   If no value is entered, a default value will be used and printed.

   **NOTE:** Patient IDs, Operator IDs and Accession Nos. may be entered using the bar code reader.

When the analysis is completed, the status light stops blinking and the instrument alerts you with an audible “beep”.

You can continue entering or editing patient information or display the results by pressing ![Up](up) at any time.

**NOTE:** If the screen has not been touched for approximately three (3) minutes the results will automatically be displayed (Fig. 5-14).

The **Calculated** tab displays the calculated parameters (Fig. 5-15).

**NOTE:** If patient temperature was input, it will be displayed in place of a calculated parameter. In this case, the pH value displayed is temperature corrected.

**NOTE:** The calculated parameter shown with the results may be configured in the setup menu (See Section 3.3.2.3).
NOTE: The resolution of the measured parameters may be configured “HIGH” (Na⁺ = 156.4 mmol/L) or “LOW” (Na⁺ = 156 mmol/L) in the Setup menu (See section 3.3.3.3).

NOTE: The OPTI LION “flags” values that are above or below the programmed ranges with an up or down arrow. If the value is outside the measurable range, a ‘HIGH’ or ‘LOW’ will be displayed and a > or < with a range printed out on the patient report.

NOTE: When a value for any measured parameter can not be determined, the display will show a series of dashes “----” and the printout will contain an error message stating that the result was suppressed.

WARNING: Treatment should never be administered based on results that are flagged on the printout.

The <Calibration> tab displays data from the cassette calibration preceding the measurement (Fig. 5-16).

15. Open the cover, remove the cassette and press to go to the next sample.

To edit the patient data, press <Patient Info>.

NOTE: The printout will automatically start when the first results are displayed. This feature may be turned off in setup (Section 3.3.1.3).
5.3 Printing Patient Reports

This menu lets you print out patient reports. You can print out individual patient results, groups of patient results, or all the results in memory.

1. From the <Ready> display, select <Data Manager>.

2. Press <Patient> (Fig. 5-17).

3. In the <Patient Measurement> screen (Fig. 5-18), press the button to display the measurement results. The sorting order within the individual columns may be changed from ascending to descending by pressing the column header.

4. To print individual results, highlight the desired measurement. To print groups of results, highlight the first measurement to be printed, press , then select the last measurement to be printed. All the measurements in between will be selected. Press to select all results.

5. Press to print your selection.

NOTE: The printout may be discontinued at any time by pressing .

6. After printing, patient data may be deleted by pressing .

- After data has been deleted, the system will return to the <Data Manager>.

NOTE: If a password has been enabled under the Setup menu, it must be entered prior to deleting data from the database.

7. Press to return to the <Ready> screen.
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6.1 Daily Maintenance

No daily maintenance is required for the OPTI® LION System.

6.2 Weekly Maintenance

Once a week, the Sample Measurement Chamber (SMC) must be cleaned. Open the top cover and clean the optics surface as well as the underside of the SMC cover with a lint-free cloth, dampened with a dilute alcohol or ammonia-based cleaner as needed. Be sure to remove all blood residue. A cotton swab may be used for cleaning the smaller parts of the SMC.

6.3 Quarterly Maintenance – Performing Intensity Calibration

1. In the <Ready> display, select <QC Manager>.
2. Select <Calibrator> (Fig. 6-1).

Fig. 6-1 Select Calibrator
3. Use the numeric keypad to enter the password (Fig. 6-2).

4. Use the alphanumeric keypad to enter the Operator ID or press \( \text{OK} \) to bypass this function (Fig. 6-3).

   NOTE: If Secure Op. IDs is activated under Setup (see Section 3.3.3.4.3) your 4-digit PIN # will be required in place of your Operator ID.

5. Enter the lot number of the Calibration Cassette located on the top surface of the cassette and press \( \text{OK} \) (Fig. 6-4).
6. At the prompt open the SMC cover by pressing the cover release button (Fig. 6-5).

7. Insert the calibration cassette into the chamber and press down to properly seat the cassette (Fig. 6-6).

8. Close the Sample Measurement Chamber cover (Fig. 6-7).
After the cover has been closed, the instrument will automatically detect the presence of the calibration cassette and begin calibration (Fig. 6-8).

9. After the calibration is complete you will be prompted to open the sample chamber cover and remove the cassette.

10. Place the calibration cassette back into its pouch immediately after removal from the instrument.

NOTE: Make sure to keep the calibration cassette with the instrument at all times.

The instrument will now prompt for a liquid QC measurement.

11. Perform a liquid QC measurement as described in section 4.5.3.

WARNING: If the liquid QC measurement is not run, patient measurements cannot be performed.

The unit will now begin printing the Calibration report showing both the old and new calibration results and calibration factors (Fig. 6-9).
6.4 Annual Maintenance

Once a year, the peristaltic pump cartridge and I/O port must be replaced to assure that your analyzer operates at peak performance.

6.4.1 Replacing Peri Pump Cartridge

To change the cartridge:

1. Open the printer cover door. The peri pump is located to the right of the printer. Remove the pump by firmly grasping the ends of the housing and pulling upward (Fig. 6-10).

![Fig. 6-10 Remove Pump Cartridge](image1)

2. Install the new pump cartridge by first rotating the flat surface on the pump motor shaft to align with the flat surface of hole (keyway) in the pump cartridge roller. Press the cartridge firmly down until it is fully seated on the housing of the instrument (Fig. 6-11).

![Fig. 6-11 Install New Cartridge](image2)

3. Press the pump cartridge roller down until it firmly seats on the shaft of the pump motor (Fig. 6-12).

![Fig. 6-12 Push on Pump Roller](image3)

4. Perform a <Pump Test> (see section 7.2.10) to ensure correct operation. Make sure the pump rotates smoothly without excessive noise. In addition, run one level of quality control. Make sure the control measurement passes without errors.
6 MAINTENANCE

6.4.2 Replacing I/O Port

To change the I/O port:

1. Open the SMC cover. Remove the black I/O port by grasping it with a hemostat or tweezers and firmly pulling upward. Discard the old part.

2. Install the new I/O port with the rounded surface pointing up and press it into the recess. When fully seated, the I/O port is approximately 1/8 inch (3mm) above the surrounding surface.

3. Perform a <Pump Test> (see section 7.2.10) to ensure correct operation. Make sure the pump rotates smoothly without excessive noise. In addition, run one level of quality control. Make sure the control measurement passes without errors.
6.5  As Needed Maintenance

6.5.1  Changing Printer Paper

The thermal printer paper supplied by OPTI Medical contains an indicator strip to alert you when the paper roll should be changed. To change the roll:

1. Open the cover on the top of the analyzer.
2. Press the paper advance button to eject any remaining paper (Fig. 6-13).
3. Remove the old roll.

4. With the OPTI LION powered on, place a new roll of paper in the chamber and thread it into the feeder. Use the diagram in the paper well to make sure the paper is inserted correctly (Fig. 6-14).

5. As soon as the printer detects the paper, it will automatically feed the paper completely through the printer. The paper advance button should only be used if the paper is present.

6. To advance paper after the initial installation, press the red paper advance button located on the left side of the printer (Fig. 6-13).

7. Close the top cover of the analyzer and tear off any excess paper (Fig. 6-15).
6.5.2 Performing Routine Cleaning

The OPTI LION Electrolyte Analyzer is designed to require very little maintenance. Routine cleaning consists of wiping the exterior analyzer surfaces with a soft, damp cloth.

*NOTE:* Never use strong or abrasive cleaners on the OPTI LION Electrolyte Analyzer.
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7 DIAGNOSTICS AND TROUBLESHOOTING

Your OPTI® LION Electrolyte Analyzer is designed to provide trouble-free service. However, any measuring device may occasionally malfunction requiring you to identify the cause of the problem and initiate corrective action.

This chapter describes OPTI LION specific error messages and recommends steps that should return your OPTI LION to operation.

If your OPTI LION does not perform correctly after conducting the basic steps outlined in this chapter, you should contact OPTI Medical Systems for technical assistance.

7.1 Error Displays

Sensors did not detect sample. Make sure sample probe is properly attached, sample probe is not submerged in serum separator gel, not clotted and does not contain air bubbles. Wait for the system to recalibrate.

- Remix sample carefully.
- Press \( \text{OK} \) to notify the system that the sample is reattached and reaspirate sample.

Unstable pH or other measured parameter.

*NOTE: This message is a warning. The analyzer will, however, display a result for the parameter concerned.*

- Remove cassette and check for aspirated bubbles.
- If bubbles are present over a sensor, do not report that parameter.

The pH (or other measured parameter) sensor is bad.

- You have the option of continuing the measurement by pressing \( \text{OK} \) or stopping by pressing \( \text{Cancel} \). If you continue, no results will be provided for the bad sensor or any calculated result, which utilizes this measurement in its calculation.
- If the error persists, run calibrator followed by liquid QC.
The peristaltic pump is getting worn.

- Press to continue measurement.
  Perform pump diagnostic (see Section 7.2.10) if this warning persists.
- If the pump diagnostic fails, replace the pump cartridge (see section 6.4).

The peristaltic pump is getting worn.

- Remove the cassette.
- Retry with a new cassette.
- Change the peristaltic pump cartridge.

The light gates detected a bubble in the sample.

- Discard the cassette and repeat measurement with new cassette.

This display only appears once prior to the three month expiration of the Intensity Calibration and acts as a reminder to run the Calibration Cassette.

- Press to continue.

The number of secure users (operator IDs) stored in memory equals 300.

- Press to continue.
- Delete unused Operator IDs from memory (See Section 3.3.3.4.3).
If Patient ID (Operator ID and/or Accession Number) is required and no patient data was input or patient data was previously edited without adding the required information, this warning will be displayed.

- Press OK to continue and edit the patient data.

If Patient ID (Operator ID and/or Accession Number) is required and still not entered, this error will be displayed.

- Press OK to edit the patient data and add the required information. A new printout will be given with the required information.

Two or more measured parameter sensors are bad.

- Press OK, discard the cassette and repeat the test with a new cassette.
- If the error persists, run calibrator followed by liquid QC.

A sample error has occurred. This may be due to a clot or blockage in the sample probe preventing sample aspiration.

- Press OK and discard cassette.

The cassette was not properly placed into the chamber.

- Open the SMC cover.
- Reinsert the cassette and verify proper seating.
- Press OK to continue.

OR

- Press Cancel to return to the <Ready> display and retry after installing a new cassette.
The cassette or its packaging is defective.
- Press \[\text{OK}\], discard the cassette and repeat test with a new cassette.
- If the error persists, run calibrator followed by liquid QC.

The instrument did not calibrate due to problems with the cassette or instrument.
- Press \[\text{OK}\], discard the cassette and repeat the test with a new cassette.

The optics or cassette are dirty.
- Remove the cassette. Inspect the cassette and optics on bottom and top plate. Clean, if necessary.
- Reinsert the cassette and press \[\text{OK}\] to rerun the test.

The cassette has been holding the calibration for more than 10 minutes without a sample being attached.
- Press \[\text{OK}\] and discard the cassette.

A sample error has occurred.
- This may be due to a clot or large air bubble if two or more sensors are unstable.
- Press \[\text{OK}\] and discard the cassette.
- Check the sample and rerun with a new cassette.
The system was not able to aspirate enough contiguous sample fluid to cover the optode sensors after multiple aspiration attempts. If a bubble was detected, the system attempted to restart the aspiration and was not able to aspirate enough sample.

- Press and discard the cassette.

The bar code was invalid (the OPTI LION either misread the bar code label or it is an invalid bar code for the OPTI LION).

- Press to retry.
- If the error message appears again, check the product package for intended use.
- Check the bar code reader (see Section 7.2.6).
- Clean the bar code reader.
  - Press in the locking detent located on the bar code reader guide.
  - Gently slide the bar code reader guide up, away from the analyzer.
  - Using a lint-free cloth dampened with a dilute alcohol or ammonia-based cleaner, gently wipe the face of the reader clean.
  - Slide the bar code reader guide down over the reader until it clicks.
  - Retry the bar code.

The bar code was invalid (the OPTI LION either misread the bar code or the product (i.e. cassette or SRC) has expired).

- Press to retry.
- If the error message appears again, check the date in <System ->Time and Date>.
- Verify the product expiration date.
7 DIAGNOSTICS AND TROUBLESHOOTING

The cassette expiration date has been reached.
- Press OK to retry.
- If the error message appears again, check the date in <System ->Time and Date>.
- Verify the product expiration date.

The cassette placed in the SMC is invalid.
- Verify that the cassette placed in the SMC is a valid calibration cassette.
- Press OK to continue.

The QC lot is invalid.
- Press OK to continue.
- Configure the control material under <Setup> and retry.

The SRC type is invalid.
- Press OK to continue.
- Remove the SRC.
- Configure the SRC data in <Setup> and retry.

The SRC expiration date has been reached.
- Press OK and remove the SRC.
- If the error message appears again, check the date in <System ->Time and Date>.
- Configure a new SRC under <Setup> and retry.
**7 DIAGNOSTICS AND TROUBLESHOOTING**

A measurement of QC materials, either liquid or SRCs, was attempted prior to setting up.

- Press OK to continue.
- Configure the SRCs and/or liquid QC material under <Setup> and retry.

The analyzer is unable to calibrate the sample light gates due to dirty optics or cassette.

- Remove and discard the cassette.
  Inspect and clean the optics glass inside the sample measurement chamber.
- Press OK to continue.
- Check the LEDs (See Section 7.2.3).

The Operator ID already exists in the database.

- Press OK to continue.
- Enter a unique Operator ID.

The PIN number does not exist in current Secure Op. ID database.

- Press OK to continue.
- Retry with a valid PIN number.

The PIN number already exists in database.

- Press OK to continue.
- Enter a unique PIN number.
7 DIAGNOSTICS AND TROUBLESHOOTING

The OPTI LION received no response from the host computer.

- Press Yes to retry.

If the problem persists:

- Check connection between the OPTI LION and the host computer.
- Check the OPTI LION’s communication configuration under <System -> Hardware>.
- Check the host computer.

The OPTI LION received a negative (NAK) response from the host computer.

- Press Yes to retry.

If the problem persists:

- Check the host computer or contact the facility IT manager.

This error may occur during an intensity calibration. The error is triggered, when the correction is greater than 10%.

To retry:

- Replace the calibration cassette.

The intensity measured during an SRC measurement is outside the limits.

- Press OK and run Calibrator.
- Repeat the SRC measurement.

One or more parameters are outside the drift limits during an SRC measurement.

- Press OK and repeat SRC measurement.
If SRC QC lockout has been activated in <Setup>, this message will be displayed if SRCs have not been run within the specified time.

- Press OK and run SRCs.

The instrument has detected an internal error.

- Discard the cassette.
- Turn the power off, wait 30 seconds and then turn the power back on.

Patient, QC and other databases were deleted.

- Press OK and the instrument will reinitialize.
- Reenter System QC, SRC and setup information.

If Control lockout has been activated in <Setup>, this message will be displayed if liquid controls have not been run within the specified time.

- Press OK and run control materials.

The temperature is out of range during any kind of measurement.

- Press OK and continue.
- If the error message appears again, check the temperature under <System - Diagnostics>.
The temperature is out of range.

- Wait for the analyzer to reach the correct temperature.
- If the analyzer does not become `<Ready>` within a reasonable time, check the temperature under `<System - Diagnostics>`.
7.2 Diagnostics

Your OPTI LION has a number of useful diagnostic programs.

From the <Ready> display, press <System Manager> and <Diagnostics> (Fig. 7-1).

The <Diagnostics> screen contains three tabs with various diagnostic functions: <Sensors>, <Control> and <Tests>.

7.2.1 Checking Versions

From the <Ready> display, press <System Manager> and <Diagnostics>.

The first option on the <Sensors> screen, <Versions> (Fig. 7-2), allows you to check the software version, version of the optical module, as well as the GUI version.
7.2.2 Checking System Temperatures

From the <Ready> display, press <System Manager> and <Diagnostics>.

The <Temperature> option lets you check the various system temperatures: <Top Plate>, <Bottom Plate> and <Ambient> (Fig. 7-3).

NOTE: If top or bottom plate temperatures are out of range, the temperature display will change to red.

![Fig. 7-3 Temperature](image)

7.2.3 Checking the LEDs

The purpose of this diagnostic is to check proper functioning of the LEDs.

From the <Ready> display, press <System Manager> and <Diagnostics>.

The following information is displayed in the <LEDs> section (Fig. 7-4):

- <Front>, <Rear>, <Ion> - fluid light gates.
- <Cassette Missetat> detector (located in cover)
- <Cassette Detect> sensor
- <SMC Cover> - this diagnostic function indicates whether the SMC cover is closed or open.

- Press Up to return to the <System> screen.

![Fig. 7-4 LEDs](image)
7.2.4 Checking the Cooling Fan

The purpose of this test is to check for proper functioning of the cooling fan.

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Control> tab.
- Press the <On/Off> button under <Fan> to start the test (Fig. 7-5).
- When <On> is selected, you should feel the draft of the fan by placing your hand over the fan at the back side of the analyzer.
- Press to return to the <System> screen.

Fig. 7-5 Cooling Fan

7.2.5 Checking the Factory Settings

This <Fset> function (Fig. 7-6) is a service area exclusively for use by authorized OPTI Medical personnel.

Fig. 7-6 Factory Settings
7.2.6 Checking the Bar Code Reader

This option allows you to check the function of the bar code reader.

From the <Ready> display, press <System Manager> and <Diagnostics>.
- Select the <Tests> tab.
- Press <Barcode> to start the test (Fig. 7-7).

- To test the bar code reader, swipe a bar code label of e.g. a sensor cassette (Fig. 7-8).

- The display will show a sequence of numbers (Fig. 7-9). Compare the numbers with those printed on the cassette bar code label. Matching information confirms the proper function of the bar code reader.
- Press OK to return to the <Tests> screen.
- Press Up to return to the <System> screen.
7.2.7  Checking the Printer

This test function lets you check for the proper functioning of the built-in thermal printer. To activate:

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Tests> tab.
- Press <Printer> to start the test (Fig. 7-10).
- The printer will output a test print.
- Check if the alphanumeric printout is legible and all the characters are properly printed.

If the printout is poor quality or defective, your printer may need replacement.

To replace the printer, follow the steps below.

- Turn the OPTI LION off.
- Remove the paper roll and pump cartridge.
- Unscrew the two thumbscrews holding the printer in place.
- Pull printer up and out towards the paper tray.
- Disconnect the cable from the receptacle.
- Install the new printer in reverse order.
7.2.8 **Checking the Optics**

This option checks the output of the optics channels. This test is designed for trained OPTI Medical service personnel.

From the *<Ready>* display, press *<System Manager>* and *<Diagnostics>*.
- Select the *<Tests>* tab.
- Press *<Optics>* to start the test (Fig. 7-11).

- Insert an SRC or press *OK* (Fig. 7-12).

The system will now check the optics (Fig. 7-13).

- At the completion of the test, a printout of the results will be printed and the *<Remove SRC>* message will be displayed (Fig. 7-14).
7.2.9 Checking the RS232 Interface

The purpose of this test is to check for proper functioning of the serial interface.

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Tests> tab.
- Press <RS232> to start the test (Fig. 7-15).

- It is important to have pins 2 and 3 (send and receive) shorted together (Fig. 7-16 and Fig. 7-17).
- Press OK and the system will send out a test string and check if it can be received.

- The instrument will display a <Pass> or <Fail> message (Fig. 7-18).
- Press OK to return to the <Tests> screen.
7.2.10 Checking the Pump Motor

The purpose of this test is to check the proper functioning of the peristaltic pump motor.

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Tests> tab.
- Press <Pump> to start the test (Fig. 7-19).

The pump will automatically step through all the speeds used during normal operation (50 to 800 pps) (Fig. 7-20) and return to the <Tests> screen.

7.2.11 Checking the Display

The purpose of this test is to check the proper operation of the display.

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Tests> tab.
- Press <Display> to start the test (Fig. 7-21).
- The display will turn red, green and blue. If this is not the case, the display is defective and needs to be replaced.
- Press Up to return to the <System> screen.
7.2.12 Checking the Touch Screen

The purpose of this test is to check the proper operation of the touch screen.

From the <Ready> display, press <System Manager> and <Diagnostics>.

- Select the <Tests> tab.
- Press <Touch> to start the test (Fig. 7-22).

- Touch the screen and the dot should appear under the touched location (Fig. 7-23).
- If not, press <Calibrate> and perform a touch calibration (Fig. 7-24).
- Press <Up> to return to the <System> screen.
- Using a finger, stylus or pointed object (e.g. clean sample probe), touch the center of the calibration mark as it moves around the screen (Fig. 7-24).

NOTE: Sharp objects may damage the screen.

- When finished press <Save>.
7.2.13 Diagnostic Reports

This option allows you to print diagnostic and configuration reports.

From the <Ready> display, press <Data Manager> to access the <Data> screen (Fig. 7-25).

The section <Diagnostic Reports> contains the following reports:

- <Patient>, <SRC>, <Controls> and <Errors>.

7.2.13.1 Patient Diagnostic Report

The <Patient> diagnostic report is available with the results after each measurement.

- To print a patient report, select <Diagnostic Reports> - <Patient> in the <Data> screen (Fig. 7-26).

- Select a patient and press Print to print calibration reports detailing the measured signal in millivolts and drifts (Fig. 7-27).

- Press Up to return to the <Data> screen.
7.2.13.2 SRC Diagnostic Report

The <SRC> diagnostic report shows details of measured signals in millivolts as well as drifts observed in the measurement.

- To print an SRC report, select <Diagnostic Reports> - <SRC> in the <Data> screen (Fig. 7-28).

- Select the desired measurement and press to print the SRC diagnostic report (Fig. 7-29).

  To print groups of results, highlight the first measurement to be printed, press , then select the last measurement to be printed. All the measurements in between will be selected.

  Press to select all results.

- Press to return to the <Data> screen.
7.2.13.3 Controls Diagnostic Report

The <Controls> diagnostic report shows details of measured signals in millivolts as well as drifts observed in the measurement.

- To print a controls report, select <Diagnostic Reports> - <Controls> in the <Data> screen (Fig. 7-30).

- Select the desired measurement and press to print the diagnostic report (Fig. 7-31).

To print groups of results, highlight the first measurement to be printed, press then select the last measurement to be printed. All the measurements in between will be selected.

Press to select all results.

- Press to return to the <Data> screen.
### 7.2.13.4 Error Report

The <Errors> menu gives you the option to print or delete the error messages from the database.

- To print an error report, select <Diagnostic Reports> - <Errors> in the <Data> screen (Fig. 7-32).

- Press **Print** to print the error messages in the database (Fig. 7-33).

- To delete the error database, press **Delete**. Confirm your choice by pressing **Yes** in the <Delete the Error Log?> screen (Fig. 7-34).

- Press **Up** to return to the <Data> screen.
7.2.13.5  Configuration Report

The <Configuration Report> reports all settings like QC ranges, reference limits, correlation factors, patient information, printout settings etc.

- To print a configuration report, select <Miscellaneous Reports> - <Configuration> in the <Data> screen (Fig. 7-35).

- Press Up to return to the <Data> screen.

NOTE: After initial setup, a configuration report should be printed and kept in a safe place for later reference.
8 PRINCIPLES OF OPERATION ........................................................... 8-1
8 PRINCIPLES OF OPERATION

Luminescence is the emission of light energy resulting from excited molecules returning to a resting state. When luminescence is initiated by light energy, it is commonly referred to as fluorescence. When a fluorescent chemical is exposed to light energy of an appropriate color, electrons in the molecules of the fluorescent chemical are excited. A very short time later, the electrons return to a resting state and in this process sometimes emit a small amount of light energy. This emitted energy is less than the excitation energy and therefore has a different color.

Fluorescent optodes (from optical electrodes) essentially measure the intensity of light emitted from fluorescent dyes. The emitted light is distinguished from the excitation light by means of optical filters. Because the excitation light energy is kept constant, the amount of emission light that results is affected only by the concentration of the analyte. The concentration of the analyte is determined by calculating the difference in fluorescence measured at a known calibration point and fluorescence measured with the sample’s unknown concentration of analyte.

The Na⁺, K⁺, Cl⁻ and iCa ion optodes are based upon the principle of Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970’s to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI LION using the measured pH.

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titration in turbid media.

The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry,

\[
\frac{I_0}{I} = \frac{10^{pK_a-pH} + 1}{10^{pK_a-pH} + R}
\]

which describes how the fluorescence emission intensity decreases as the blood pH is increased above the dye’s characteristic pKa. R is the ratio of minimum fluorescent intensity (pH >> pKa) to maximum fluorescent intensity (pH << pKa). pH optodes do not need a reference electrode to measure pH, however, they exhibit a small sensitivity to the ionic strength of the sample being measured.

The OPTI LION is a microprocessor-based instrument measuring optical fluorescence. A disposable, single-use cassette contains all the elements needed for calibration, sample measurement and waste containment. After reading the calibration information specific to a cassette into the instrument by ‘swiping’ the cassette package through a convenient bar code reader, the cassette is placed in the measurement chamber. The analyzer warms the cassette to 37.0 ± 0.1°C, and then performs a dry calibration on the pH and ion channels. When calibration is verified, the analyzer aspirates the blood sample into the cassette and over the optode sensors.
and measures the fluorescence emission of the optodes after they have equilibrated with the blood sample.

After a single measurement, the cassette, with the blood sample safely locked away, is removed from the analyzer and discarded. No reagents, blood or waste ever enter the OPTI LION itself.

During each measurement, light originating from lamps in the analyzer is passed through optical filters so that photons of a specific color are transmitted to the sensors, causing them to emit fluorescence. The intensity of this emitted light depends upon the hydrogen ion concentration (pH) and electrolyte concentration (Na⁺, K⁺, Cl⁻, iCa) of the blood in direct contact with the sensors, as described above. The light emitted by the fluorescent sensors is measured by the analyzer after passing through lenses and additional optical components. A filter is used to isolate specific colors of interest from this returning light for measurement by a light detector.

The optical signal of the detectors is converted by the microprocessor to a numerical readout in conventional units of measure and displayed on the front of the device.
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9 SUPPLIES

Each OPTI® LION is shipped with maintenance supplies and other accessories. Below is a listing of all necessary supplies and accessories. To order replacement supplies and accessories, contact your local authorized OPTI Medical Distributor or, in the U.S., call the OPTI Medical Order Entry Department at 1-800-490-6784 (OPTI) Monday through Friday, 8 AM to 5 PM eastern time. Our Order Entry representatives will gladly provide any assistance you may require.

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1 Analyzer</td>
<td></td>
</tr>
<tr>
<td>OPTI LION Electrolyte Analyzer with Accessory Kit</td>
<td>GD7200</td>
</tr>
<tr>
<td>9.2 Cassettes</td>
<td></td>
</tr>
<tr>
<td>OPTI LION E-Plus Cassette (25 Per Box)</td>
<td>BP7507</td>
</tr>
<tr>
<td>9.3 Controls/Calibrators</td>
<td></td>
</tr>
<tr>
<td>Standard Reference Cassette (SRC) - Level 1</td>
<td>BP7604</td>
</tr>
<tr>
<td>Standard Reference Cassette (SRC) - Level 2</td>
<td>BP7605</td>
</tr>
<tr>
<td>Standard Reference Cassette (SRC) - Level 3</td>
<td>BP7606</td>
</tr>
<tr>
<td>OPTI CHECK LYTES, Trilevel</td>
<td>HP0070</td>
</tr>
<tr>
<td>Calibration Cassette</td>
<td></td>
</tr>
<tr>
<td>9.4 Consumable Items</td>
<td></td>
</tr>
<tr>
<td>Printer Paper</td>
<td>HP0070</td>
</tr>
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</table>
## 9 SUPPLIES

<table>
<thead>
<tr>
<th>Description</th>
<th>Part Number</th>
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<tr>
<td><strong>9.5 Accessories</strong></td>
<td></td>
</tr>
<tr>
<td>CF Export Kit</td>
<td>BP7140</td>
</tr>
<tr>
<td>Cable, Interface, OPTI LION to PC</td>
<td>BK7002</td>
</tr>
<tr>
<td><strong>9.6 Manuals</strong></td>
<td></td>
</tr>
<tr>
<td>Operator’s Manual</td>
<td>PD7200</td>
</tr>
<tr>
<td>Service Manual</td>
<td>PD7201</td>
</tr>
<tr>
<td><strong>9.7 Spare Parts</strong></td>
<td></td>
</tr>
<tr>
<td>Peripump Cartridge</td>
<td>BP7012</td>
</tr>
<tr>
<td>Power Supply</td>
<td>EI7004</td>
</tr>
<tr>
<td>Power Cord</td>
<td>EX0197</td>
</tr>
<tr>
<td>Seal SMC I/O Port</td>
<td>RE7030</td>
</tr>
<tr>
<td>Printer Assembly</td>
<td>BP7090</td>
</tr>
</tbody>
</table>
9.8 **Technical Assistance**

Most often, problems with your OPTI LION can be resolved over the telephone, getting the analyzer back in service within minutes. Our technicians have the training and experience necessary to provide dependable technical assistance.

The OPTI Medical Service Hotline (U.S. market only) is staffed to provide prompt troubleshooting assistance seven (7) days per week, twenty-four (24) hours per day. Should you need troubleshooting assistance or application information regarding your OPTI analyzer just contact the OPTI Medical Service Hotline for assistance.

In the U.S., call **1-800-490-6784 (OPTI)** to request technical assistance from OPTI Medical Systems.

Should you require additional service support, our OPTI Medical Service Hotline can provide complete details on all available service options and ensure that any instrument downtime is minimized.

9.9 **Warranty Registration (U.S. Market Only)**

After successful completion of the installation of your new OPTI LION, complete the enclosed *Installation and Instrument Warranty Report* form. Return the completed form to OPTI Medical Systems to ensure warranty support if you ever need warranty assistance. The model and serial numbers of your OPTI LION are on the bottom panel of the unit.

Please read the Instrument Warranty Terms and Conditions and become familiar with this agreement.

Each new analyzer purchased has a one year warranty from the date the analyzer is placed into service.

Contact the OPTI Medical Service Hotline for any assistance regarding warranty or support.
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Measurement Range

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Display Resolution (Lo/Hi)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>100 to 190</td>
<td>1/0.1</td>
<td>mM</td>
</tr>
<tr>
<td>K⁺</td>
<td>1.0 to 9.5</td>
<td>0.1/0.01</td>
<td>mM</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>65 to 145</td>
<td>1/0.1</td>
<td>mM</td>
</tr>
<tr>
<td>iCa</td>
<td>0.3 to 2.0</td>
<td>0.01</td>
<td>mM</td>
</tr>
<tr>
<td>pH</td>
<td>6.8 to 8.0</td>
<td>0.01/0.001</td>
<td>pH units</td>
</tr>
</tbody>
</table>

Operating Altitude

Up to 3048m (10,000ft)

Pollution Degree

Degree 2, normal indoor laboratory environment. Air contains only non-conductive pollutants with occasional condensation.

Operating Parameters

- Minimum Sample Size: 125µL
- Sample Type: heparinized whole blood, plasma or serum
- Sample Application: sample collection tube, sample cup and syringe
- Sample Input: automatic aspiration
- Analysis Time: < 2 minutes
- Ambient Temperature Range: 10 °C - 32 °C (50 °F - 90 °F)
- Relative Humidity Range: 5% - 95% (non-condensing)
- Type of Measurement: optical fluorescence
### Input Values

- **Operator ID**: 11 characters (alphanumeric)
- **Patient ID**: 15 characters (alphanumeric)
- **Accession Number**: 12 characters (alphanumeric)
- **Patient Temperature**: 14 – 44°C (58 - 111°F)
- **Patient Sex**: male, female or ? (Unknown)
- **Date of Birth**: DD-MMM-YYYY
- **Sample Type**: Whole blood, serum, plasma
- **User Field 1, 2 and 3**: 9 digits

### Calculated Values

- **Hydrogen ion concentration (cH⁺)**: 10.0 - 1000.0 nmol/L
- **nCa**: 0.22 - 2.79 mmol/L

### Temperature Corrected Values

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Display Resolution (Lo/Hi)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH⁺</td>
<td>6.8 - 8.0</td>
<td>0.01/0.001</td>
<td>pH units</td>
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### Reference Ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>Range</th>
<th>Reference Source</th>
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</thead>
<tbody>
<tr>
<td>Hydrogen ion concentration (cH⁺)</td>
<td>nmol/L</td>
<td>36 to 44</td>
<td>Tietz¹, page 2201</td>
</tr>
</tbody>
</table>

Data Management

Printout: Built-in thermoprinter
Interface (serial): RS232C
Format: ASCII and ASTM
Storage: Storage capacity is 200 patient records, 35 QC and SRC data per level.

RS232C – Pin Configuration

**REAR VIEW OF OPTI LION**

<table>
<thead>
<tr>
<th>Pin Nr</th>
<th>Designation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>2</td>
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<td>Receive</td>
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<td>3</td>
<td>TxD</td>
<td>Transmit</td>
</tr>
<tr>
<td>4</td>
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</tr>
<tr>
<td>5</td>
<td>GND</td>
<td>Signal Ground</td>
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<td>6</td>
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</tr>
<tr>
<td>9</td>
<td>No Connection</td>
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</tr>
</tbody>
</table>

Mains Supply for External Power Supply

100 ± 10% VAC to 240 ± 10% VAC, 50/60 Hz

Overvoltage Category

Category II when connected to a branch circuit
**Dimensions and Weight**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>4.7&quot;</td>
<td>12.0 cm</td>
</tr>
<tr>
<td>Width</td>
<td>14.2&quot;</td>
<td>36.2 cm</td>
</tr>
<tr>
<td>Depth</td>
<td>9.1&quot;</td>
<td>23.0 cm</td>
</tr>
<tr>
<td>Weight</td>
<td>10 lbs</td>
<td>4.5 kg</td>
</tr>
</tbody>
</table>

**Classifications**

- Approvals: UL3101-1, CAN/CSA C22.2 NO.1010.1, CE, FCC Class A
- Mode of Operation: Continuous Operation
- Explosion Protection: This device is not designed for operation in explosive environments

**Calculated Parameters**


**Temperature**

\[
T[°F] = \frac{9}{5} \cdot T[°C] + 32
\]

\[
T[°C] = \frac{5}{9} (T[°F] - 32)
\]

---

Units Used in Measured and Input Parameters for Calculations

- Na..............mmol/L
- K.............. mmol/L
- Cl ..............mmol/L
- Ca..............mmol/L
- pH..............pH-unit

Conversion Table for Units³

<table>
<thead>
<tr>
<th>Unit</th>
<th>Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>ionized Calcium (iCa)</td>
<td>1 mmol/L = 4.008 mg/dL = 2mEq/L</td>
</tr>
</tbody>
</table>

Equations⁴

\[ cH^+ = 10^{(9 \cdot \text{pH})} \]  
\[ \text{pH}^t = \text{pH} - [0.0147 + 0.0065 \cdot (\text{pH} - 7.4)] \cdot (t - 37) \]  
\[ cH^t = 10^{(9 \cdot \text{pH}^t)} \]

**nCa**

The ionized calcium value normalized to pH = 7.40.

For blood:

\[ nCa \,(pH = 7.4) = iCa \times 10^{0.22\times(pH-7.4)} \] [mmol/L]

For plasma or serum:

\[ nCa \,(pH = 7.4) = iCa \times 10^{0.24\times(pH-7.4)} \] [mmol/L]
**APPENDIX C - MISCELLANEOUS FORMS**

**Maintenance Log**

Month: ___________________________ Year: ______________

<table>
<thead>
<tr>
<th>WEEKLY:</th>
<th>Week: 1</th>
<th>Week: 2</th>
<th>Week: 3</th>
<th>Week: 4</th>
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<tbody>
<tr>
<td>Clean Sample</td>
<td>Date</td>
<td>Initial</td>
<td>Date</td>
<td>Initial</td>
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<tr>
<td>Measurement Chamber</td>
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<tr>
<td>Perform Intensity</td>
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<td>Date</td>
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<td>Clean analyzer</td>
<td>Date</td>
<td>Initial</td>
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<td>paper</td>
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Reviewed by: __________________

Date: __________________
Method Accuracy Sheet 1

Hospital Name:_________________________________________________________

Department:____________________________________________________________

Performed by:___________________________________________________________ Date:________________________

Current Analyzer/Method:________________________________________ Serial Number:________________________

New Analyzer/Method:____________________________________ Serial Number:________________________

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<th>LION pH</th>
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</tbody>
</table>

Comments:______________________________________________________________

Reviewed by:________________________________________________________ Date:________________________
# Method Accuracy Sheet 2

Hospital Name: 

Department: 

Performed by:  Date: 

Test:  Test Units: 

Current Analyzer/Method:  Serial Number: 

New Analyzer/Method:  Serial Number: 

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Sample Identification</th>
<th>Reference Test Results</th>
<th>New Instrument Test Results</th>
<th>Delta</th>
<th>Comments</th>
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<tbody>
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Comments:

Reviewed by:  Date:
**Patient Entry Log**

<table>
<thead>
<tr>
<th>Sample</th>
<th>DateTime</th>
<th>OP ID</th>
<th>Pat ID</th>
<th>Na⁺</th>
<th>K⁺</th>
<th>Cl⁻</th>
<th>iCa</th>
<th>pH</th>
<th>Review</th>
</tr>
</thead>
</table>

Reference Ranges:

- Na⁺: mEq/L
- K⁺: mEq/L
- Cl⁻: mEq/L
- iCa: mEq/L
- pH

*Note: Reference Ranges to be entered by user*

**Hospital Name:**

- **Performed by:**
- **Reviewed by:**
- **Date:**

**Reference Ranges:**

- **Na⁺:** mEq/L
- **K⁺:** mEq/L
- **Cl⁻:** mEq/L
- **iCa:** mEq/L
Basic Patient Report

OPTI LION
Patient Report
DD-MMM-YY HH:MM

Pat. ID: 123456789012345
Acc. No.: 123456789012
Sample No.: 2345
Na+ 140.2 mmol/L
K+ 3.67 mmol/L
Cl– 96.3 mmol/L
iCa 1.13 mmol/L
pH 7.350

ENTERED PARAMETERS
DOB 04-May-59
Temp 38.5 °C
Sex Male

Operator ID: 123456789012
S/N: 123456 LOT: 123456

Reference Limits
Na+ 135.0 – 145.0 mmol/L
K+ 3.60 – 5.10 mmol/L
Cl– 95.0 – 115.0 mmol/L
iCa 1.12 – 1.32 mmol/L
pH 7.200 – 7.600

MESSAGES
Reminder: Run SRCs today
**SRC Measurement Report**

-----------------------------
OPTI LION
SRC Measurement
DD–MMM–YY HH:MM

Level: 1
SRC ID:XXXXX Exp: MMMYY

<table>
<thead>
<tr>
<th>TEST</th>
<th>RESULT</th>
<th>LIMITS</th>
<th>OK?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na+</td>
<td>125.0</td>
<td>123.0–127.0</td>
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</tr>
<tr>
<td>K+</td>
<td>2.56</td>
<td>2.20–2.80</td>
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</tr>
<tr>
<td>Cl–</td>
<td>80.1</td>
<td>78.0–82.0</td>
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</tr>
<tr>
<td>iCa</td>
<td>1.80</td>
<td>1.70–1.90</td>
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<tr>
<td>pH</td>
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<td>7.080–7.120</td>
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</tbody>
</table>

SRC Test Result: PASS

Operator ID:123456789012
S/N:123456

-----------------------------
### SRC Statistics Report

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<th>Na</th>
<th>K</th>
<th>OK?</th>
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Mean: 7.107

SD: 0.015 1.9 1.7

CV%: 0.21% 2.8% 3.0
## Controls Measurement Report

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Control Test Result: PASS

Store to Database: YES

Operator ID: 123456789012
SN: 1234 Lot: 123456

Reminder: Run SRCs Today
## Controls Statistics Report

**OPTI LION**

Controls Statistics

DD MMM YY HH:MM

Level: 1 OPTI-check Lytes

QCLot: XXXX Exp: MMMYY

CassLot: XXXXXX

S/N: XXXX

Number run: 26

Number ok: 26

Limits

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<th>K</th>
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Mean: 7.123 69.7 73.6

SD: 0.017 1.6 1.2

CV%: 0.23% 0.3% 0.4%
## Configuration Report

**NOTE:** The values and settings shown are for example purposes only. Please refer to your particular analyzer’s configuration report for its correct values and settings.

### OPTI LION Configuration Report

- **DD-MM-YY HH:MM**: 
- **S/N**: XXXXX
- **Version**: ABCX.XX

### Patient Info -
- **Pat.ID**: ON / Opt.
- **Oper.ID**: ON / Opt.
- **AccNum.**: ON / Opt.
- **DOB**: ON
- **Temp.**: ON
- **Sex**: ON
- **Sample Type**: ON
- **User Field1**: ON
- **User Field2**: ON
- **User Field3**: ON

### Reference Limits -
- **Na+**: 135.0-145.0 mmol/L
- **K+**: 3.50- 5.10 mmol/L
- **Cl-**: 95.0-115.0 mmol/L
- **iCa**: 1.12- 1.32 mmol/L

### Controls Info -
- **Lev. 1 LimMin LimMax**: 
- **Na+**: 110.0-120.0 mmol/L
- **K+**: 2.50- 3.30 mmol/L
- **Cl-**: 69.0- 79.0 mmol/L
- **iCa**: 1.65- 2.15 mmol/L
- **pH**: 7.160-7.280
- **QCLot**: 9169 Exp: Jan08

### Printouts -
- **Patient**: ON, copies 1
- **Calib.**: OFF

### Security -
- **Password**: ENABLED
- **QC Lockout**:
  - **SRC Levels**: 0
  - **QC Levels**: 0

### Miscellaneous
- **Units** -
  - **Temp**: Celcius
  - **Time**: 24-hour
  - **pH**
  - **iCa**: mmol/L
  - **Resolution**: High

### Correlation Factors -
- **Normal Cassettes**
  - **Slope**: 1.000
  - **Offset**: 0.0

### Communications -
- **Baud**: 9600
- **Format**: RS232/ASCII
- **Backlight Auto-Off**: 60 minutes
- **Language**: English

### FSET Values -
- **Version**: X.XX
- **IDAC1**: 2856
- **IDAC2**: 2912
- **IDAC3**: 2400
- **S/N**: XXXX

### CH 1 FalseDry
- **CH 1 CalIntensity**: 220613
- **CH 1 Dry Scalar**: 1.0117
- **CH 1 FalseDry**: 1150
- **CH 1 FalseWet**: 1523
- **CH 1 FalseWet**: 7466

### CH 2 FalseDry
- **CH 2 CalIntensity**: 170840
- **CH 2 Dry Scalar**: 0.9894
- **CH 2 FalseDry**: 1529
- **CH 2 FalseWet**: 1260
- **CH 2 FalseWet**: 3946

### CH 3 FalseDry
- **CH 3 CalIntensity**: 250893
- **CH 3 Dry Scalar**: 0.9917
- **CH 3 FalseDry**: 2285
- **CH 3 FalseWet**: 1523
- **CH 3 FalseWet**: 7372

### CH 4 FalseDry
- **CH 4 CalIntensity**: 408594
- **CH 4 Dry Scalar**: 1.0000
- **CH 4 FalseDry**: 7466
- **CH 4 FalseWet**: 1260
- **CH 4 FalseWet**: 3946

### CH 5 FalseDry
- **CH 5 CalIntensity**: 193486
- **CH 5 Dry Scalar**: 0.9899
- **CH 5 FalseDry**: 2912
- **CH 5 FalseWet**: 2285
- **CH 5 FalseWet**: 7372

### CH 6 FalseDry
- **CH 6 CalIntensity**: 468134
- **CH 6 Dry Scalar**: 1.0117
- **CH 6 FalseDry**: 2400
- **CH 6 FalseWet**: 2912
- **CH 6 FalseWet**: 2285

### CH 1 CalIntensity
- **Version**: 3
- **Printer Fix**: Yes
- **I1**: 32
- **I2**: 33
- **I3**: 63
- **I4**: 101
- **I5**: 24
- **I6**: 57

### LED Gains
- **I1**: HI
- **I2**: HI
- **I3**: HI
- **I4**: HI
- **I5**: HI
- **I6**: HI
Error Report

-------------------
OPTI LION
ERROR Report
DD-MM-YY  HH:MM
S/N: XXXXX
Version: ABCX.XX

DDMM YY     HH:MM
ERROR-Cassette Misseat 1
DDMM YY     HH:MM
Warning-Bubble Detected
DDMM YY     HH:MM
ERROR-Short Sample
DDMM YY     HH:MM
Memory Error

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